VIRGINIA DEPARTMENT OF HEALTH FOOD REGULATIONS

March 2002 Virginia Department of Health

Part I

Definitions and Purpose

Article 1

Definitions

12 VAC 5-421-10. Definitions.

The following words and terms, when used in this regulation, shall have the following meanings, unless the context clearly indicates otherwise.

"Accredited Program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards that certify individuals. "Accredited program" refers to the certification process and is a designation based upon an independent evaluation of factors such as the sponsor's mission; organizational structure; staff resources; revenue sources; policies; public information regarding program scope, eligibility requirements, re-certification, discipline and grievance procedures; and test development and administration. "Accredited program" does not refer to training functions or educational programs.

"Additive" means either a: "Food additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 201(s) and 21 CFR 170; or a, "Color additive" having the meaning stated in the Federal Food, Drug, and Cosmetic Act § 201(t) and 21 CFR 70.

"Adulterated" has the meaning stated in the Federal Food, Drug, and Cosmetic Act, § 402.

"Agent" means a legally authorized representative of the owner.

"Agent of the commissioner" means the district or local health director, unless otherwise stipulated.

"Approved" means acceptable to the Department based on a determination of conformity with principles, practices, and generally recognized standards that protect public health.

"Approved water supply" means a waterworks which has a valid waterworks operation permit from the department or a water supply which is evaluated, tested and if found in reasonable compliance with the Private Well Regulations (12 VAC 5-630), accepted and approved by the director or the director's designee.

" a_w " means water activity which is a measure of the free moisture in a food, is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature, and is indicated by the symbol a_w .

"Bed and breakfast" means a tourist home that serves meals.

"Beverage" means a liquid for drinking, including water.

"Board" means the State Board of Health.

"Bottled drinking water" means water that is sealed in bottles, packages, or other containers and offered for sale for human consumption.

"Building official" means a representative of the Department of Housing and Community Development.

"Certification number" means a unique combination of letters and numbers assigned by a shellfish control authority to a molluscan shellfish dealer according to the provisions of the National Shellfish Sanitation Program.

"CIP" means cleaned in place by the circulation or flowing by mechanical means through a piping system of a detergent solution, water rinse, and sanitizing solution onto or over equipment surfaces that require cleaning, such as the method used, in part, to clean and sanitize a frozen dessert machine. CIP does not include the cleaning of equipment such as band saws, slicers or mixers that are subjected to in-place manual cleaning without the use of a CIP system.

"CFR" means Code of Federal Regulations. Citations in these regulations to the CFR refer sequentially to the Title, Part, and Section numbers, such as 21 CFR 178.1010 refers to Title 21, Part 178, Section 1010.

"Code of Federal Regulations" means the compilation of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government which:

- 1. Is published annually by the U.S. Government Printing Office; and
- 2. Contains FDA rules in 21 CFR, USDA rules in 7 CFR and 9 CFR, and EPA rules in 40 CFR.

"Comminuted" means reduced in size by methods including chopping, flaking, grinding, or mincing. "Comminuted" includes fish or meat products that are reduced in size and restructured or reformulated such as gefilte fish, gyros, ground beef, and sausage; and a mixture of 2 or more types of meat that have been reduced in size and combined, such as sausages made from 2 or more meats.

"Commissary" means a catering establishment, restaurant, or any other place in which food, food containers or supplies are kept, handled, prepared, packaged or stored for distribution to satellite operations.

"Commissioner" means the State Health Commissioner, his duly designated officer or his agent.

"Confirmed disease outbreak" means a foodborne disease outbreak in which laboratory analysis of appropriate specimens identifies a causative organism or chemical and epidemiological analysis implicates the food as the source of the illness.

"Consumer" means a person who is a member of the public, takes possession of food, is not functioning in the capacity of an operator of a food establishment or food processing plant, and does not offer the food for resale.

"Corrosion-resistant materials" means a material that maintains acceptable surface cleanability characteristics under prolonged influence of the food to be contacted, the normal use of cleaning compounds and sanitizing solutions, and other conditions of the use environment.

"Critical control point" means a point or procedure in a specific food system where loss of control may result in an unacceptable health risk.

"Critical item" means a provision of these regulations that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental degradation.

"Critical limit" means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to minimize the risk that the identified food safety hazard may occur.

"Delicatessen" means a store where ready to eat products such as cooked meats, prepared salads, etc. are sold for off-premises consumption.

"Department" means the State Health Department.

"Director" means the district or local health director.

"Drinking water" means water that meets the requirements of the Virginia Waterworks Regulations (12 VAC 5-590). Drinking water is traditionally known as "potable water." Drinking water includes the term water except where the term used connotes that the water is not potable, such as "boiler water," "mop water," "rainwater," "wastewater," and "nondrinking" water.

"Dry storage area" means a room or area designated for the storage of packaged or containerized bulk food that is not potentially hazardous and dry goods such as single-service items.

"Easily cleanable" means a characteristic of a surface that:

- 1. Allows effective removal of soil by normal cleaning methods;
- 2. Is dependent on the material, design, construction, and installation of the surface; and
- 3. Varies with the likelihood of the surface's role in introducing pathogenic or toxigenic agents or other contaminants into food based on the surface's approved placement, purpose, and use.

"Easily cleanable" includes a tiered application of the criteria that qualify the surface as easily cleanable as specified above to different situations in which varying degrees of cleanability are required such as:

- 1. The appropriateness of stainless steel for a food preparation surface as opposed to the lack of need for stainless steel to be used for floors or for tables used for consumer dining; or
- 2. The need for a different degree of cleanability for a utilitarian attachment or accessory in the kitchen as opposed to a decorative attachment or accessory in the consumer dining area.

"Easily movable" means:

- 1. Portable (weighing 30 pounds or less); mounted on casters, gliders, or rollers; or provided with a mechanical means to safely tilt a unit of equipment for cleaning; and
- 2. Having no utility connection, a utility connection that disconnects quickly, or a flexible utility connection line of sufficient length to allow the equipment to be moved for cleaning of the equipment and adjacent area.

"Employee" means the permit holder, person in charge, person having supervisory or management duties, person on the payroll, family member, volunteer, person performing work under contractual agreement, or other person working in a food establishment.

"EPA" means the U.S. Environmental Protection Agency.

"Equipment" means an article that is used in the operation of a food establishment. "Equipment" includes, but is not limited to, items such as a freezer, grinder, hood, ice maker, meat block, mixer, oven, reach-in refrigerator, scale, sink, slicer, stove, table, temperature measuring device for ambient air, vending machine, or warewashing machine.

" F" means degrees Fahrenheit.

"Fish" means: fresh or saltwater finfish, crustaceans, and other forms of aquatic life (including alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals; all mollusks, if such animal life is intended for human consumption; and, includes any edible human food product derived in whole or in part from fish, including fish that has been processed in any manner.

"Food" means a raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption.

"Foodborne disease outbreak" means the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.

"Food-contact surface" means a surface of equipment or a utensil with which food normally comes into contact, or a surface of equipment or a utensil from which food may drain, drip, or splash into a food, or onto a surface normally in contact with food.

"Food employee" means an individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.

"Food establishment" means an operation that stores, prepares, packages, serves, vends, or otherwise provides food for human consumption:

- 1. Such as a restaurant; satellite or catered feeding location; catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people; market; vending location; conveyance used to transport people; institution; or food bank; and
- 2. That relinquishes possession of food to a consumer directly, or indirectly through a delivery service such as home delivery of grocery orders or restaurant takeout orders, or delivery service that is provided by common carriers.

"Food establishment" includes:

- 1. An element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location; and,
- 2. An operation that is conducted in a mobile, stationary, temporary, or permanent facility or location; where consumption is on or off the premises; and regardless of whether there is a charge for the food.
- 3. A bed and breakfast operation that does not meet the exemption criteria identified in paragraph 6 under "Food establishment does not include" or a bed and breakfast operation that meets the exemption requirements but chooses to be regulated under these regulations.

"Food establishment" does not include:

- 1. An establishment that offers only prepackaged foods that are not potentially hazardous;
- 2. A produce stand that only offers whole, uncut fresh fruits and vegetables;
- 3. A food processing plant;
- 4. A kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law and if the consumer is informed by a clearly visible placard at the sales or service location that the food is prepared in a kitchen that is not subject to regulation and inspection by the regulatory authority;
- 5. An area where food that is prepared as specified in 4 above of this definition is sold or offered for human consumption;
- 6. A kitchen in a private home, such as a family day-care provider serving 12 or fewer recipients; or a bed-and-breakfast operation that prepares and offers food only to guests if the home is owner occupied, the number of available guest bedrooms does not exceed 6, breakfast is the only meal offered, the number of guests served does not exceed 18, and the consumer is informed by statements contained in published advertisements, mailed brochures, and placards posted at the registration area that the food is prepared in a kitchen that is, by these regulations, exempt from this chapter; or
- 7. A private home that receives catered or home-delivered food.

"Food processing plant" means a commercial operation that manufactures, packages, labels, or stores food for human consumption and does not provide food directly to a consumer.

"Game animal" means an animal, the products of which are food, that is not classified as: cattle, sheep, swine, goat, horse, mule, or other equine in 9 CFR Subchapter A - Mandatory Meat Inspection, Part 301; as poultry in 9 CFR Subchapter C - Mandatory Poultry Products Inspection, Part 381; or as Fish. Game animal includes mammals such as reindeer, elk, deer, antelope, water buffalo, bison, rabbit, squirrel, opossum, raccoon, nutria, or muskrat and nonaquatic reptiles such as land snakes. Game animal does not include ratites such as ostrich, emu, and rhea.

"General use pesticide" means a pesticide that is not classified by EPA for restricted use as specified in 40 CFR 152.175.

"Grade A standards" means the requirements of the USPHS/FDA "Grade A Pasteurized Milk Ordinance" and "Grade A Condensed and Dry Milk Ordinance" with which certain fluid and dry milk and milk products comply.

"Group residence" means a private or public housing corporation or institutional facility that provides living quarters and meals. Group residence includes a domicile for unrelated persons such as a retirement home or a long-term health care facility.

"HACCP Plan" means a written document that delineates the formal procedures for following the Hazard Analysis Critical Control Point principles developed by The National Advisory Committee on Microbiological Criteria for Foods.

"Hazard" means a biological, chemical, or physical property that may cause an unacceptable consumer health risk.

"Hermetically sealed container" means a container that is designed and intended to be secure against the entry of microorganisms and, in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing.

"Highly susceptible population" means a group of persons who are more likely than other populations to experience foodborne disease because they are immunocompromised or older adults and in a facility that provides health care or assisted living services, such as a hospital or nursing home; or preschool age children in a facility that provides custodial care, such as a day care center.

"Hot water" means water at a temperature of 110° F. or higher unless otherwise stated.

"Imminent health hazard" means a significant threat or danger to health that is considered to exist when there is evidence sufficient to show that a product, practice, circumstance, or event creates a

situation that requires immediate correction or cessation of operation to prevent injury based on the number of potential injuries, and the nature, severity, and duration of the anticipated injury.

"Injected" means tenderizing a meat with deep penetration or injecting the meat such as with juices which may be referred to as "injecting," "pinning," or "stitch pumping". During injection infectious or toxigenic microorganisms may be introduced from its surface to its interior.

"Juice", when used in the context of food safety, means the aqueous liquid expressed or extracted from one or more fruits or vegetables, purées of the edible portions of one or more fruits or vegetables, or any concentrate of such liquid or purée. This definition does not apply to standards of identity.

"Kitchenware" means food preparation and storage utensils.

"Law" means applicable local, state, and federal statutes, regulations, and ordinances.

"Linens" means fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves.

"Meat" means the flesh of animals used as food including the dressed flesh of cattle, swine, sheep, or goats and other edible animals, except fish, poultry, and wild game animals as specified under subsections 12 VAC 5-421-330 A 3 and 4.

"mg/L" means milligrams per liter, which is the metric equivalent of parts per million (ppm).

"Molluscan shellfish" means any edible species of fresh or frozen oysters, clams, mussels, and scallops or edible portions thereof, except when the scallop product consists only of the shucked adductor muscle.

"Occasional" means not more than one time per week, and not in excess of two days duration.

"Organization" means any one of the following:

- 1. A volunteer fire department or rescue squad or auxiliary unit thereof which has been recognized in accordance with § 15.2-955 by an ordinance or resolution of the political subdivision where the volunteer fire department or rescue squad is located as being a part of the safety program of such political subdivision;
- 2. An organization operated exclusively for religious, charitable, community or educational purposes;
- 3. An association of war veterans or auxiliary units thereof organized in the United States;
- 4. A fraternal association or corporation operating under the lodge system;

5. A local chamber of commerce; or

6. A nonprofit organization that raises funds by conducting raffles which generate annual gross receipts of less than \$75,000, provided such gross receipts from the raffle, less expenses and prizes, are used exclusively for charitable, educational, religious or community purposes.

"Packaged" means bottled, canned, cartoned, securely bagged, or securely wrapped, whether packaged in a food establishment or a food processing plant.

"Permit" means a license issued by the regulatory authority that authorizes a person to operate a food establishment.

"Permit holder" means the entity that is legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person, and possesses a valid permit to operate a food establishment.

"Person" means an association, a corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.

"Person in charge" means the individual present at a food establishment who is responsible for the operation at the time of inspection.

"Personal care items" means items or substances that may be poisonous, toxic, or a source of contamination and are used to maintain or enhance a person's health, hygiene, or appearance. Personal care items include items such as medicines; first aid supplies; and other items such as cosmetics, and toiletries such as toothpaste and mouthwash.

"pH" means the symbol for the negative logarithm of the hydrogen ion concentration, which is a measure of the degree of acidity or alkalinity of a solution.

"Physical facilities" means the structure and interior surfaces of a food establishment including accessories such as soap and towel dispensers and attachments such as light fixtures and heating or air conditioning system vents.

"Plumbing fixture" means a receptacle or device that is permanently or temporarily connected to the water distribution system of the premises and demands a supply of water from the system or discharges used water, waste materials, or sewage directly or indirectly to the drainage system of the premises.

"Plumbing system" means the water supply and distribution pipes; plumbing fixtures and traps; soil, waste, and vent pipes; sanitary and storm sewers and building drains, including their respective connections, devices, and appurtenances within the premises; and water-treating equipment.

"Poisonous or toxic materials" means substances that are not intended for ingestion and are included in four categories:

- 1. Cleaners and sanitizers, which include cleaning and sanitizing agents and agents such as caustics, acids, drying agents, polishes, and other chemicals;
- 2. Pesticides which include substances such as insecticides and rodenticides;
- 3. Substances necessary for the operation and maintenance of the establishment such as nonfood grade lubricants, paints, and personal care items that may be deleterious to health; and
- 4. Substances that are not necessary for the operation and maintenance of the establishment and are on the premises for retail sale, such as petroleum products and paints.

"Potentially hazardous food" means a food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting:

- 1. The rapid and progressive growth of infectious or toxigenic microorganisms;
- 2. The growth and toxin production of Clostridium botulinum; or
- 3. In raw shell eggs, the growth of Salmonella Enteritidis.

"Potentially hazardous food" includes an animal food (a food of animal origin) that is raw or heattreated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified above in this definition.

"Potentially hazardous food" does not include:

- 1. An air-cooled hard-boiled egg with shell intact;
- 2. A food with an a_w value of 0.85 or less;

- 3. A food with a pH level of 4.6 or below when measured at 24°C (75°F);
- 4. A food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution; and
- 5. A food for which laboratory evidence demonstrates that the rapid and progressive growth of infectious or toxigenic microorganisms or the growth of S. Enteritidis in eggs or C. botulinum can not occur, such as a food that has an a_w and a pH that exceed the levels specified in this definition and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms.
- 6. A food that does not support the growth of microorganisms as specified above in this definition even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

"Poultry" means any domesticated bird (chickens, turkeys, ducks, geese, or guineas), whether live or dead, as defined in 9 CFR 381 Poultry Products Inspection Regulations; and, any migratory waterfowl, game bird, or squab such as pheasant, partridge, quail, grouse, or guineas, whether live or dead, as defined in 9 CFR 362 Voluntary Poultry Inspection Program.

"Premises" means the physical facility, its contents, and the contiguous land or property under the control of the permit holder; or the physical facility, its contents, and the land or property which are under the control of the permit holder and may impact food establishment personnel, facilities, or operations, if a food establishment is only one component of a larger operation such as a health care facility, hotel, motel, school, recreational camp, or prison.

"Primal cut" means a basic major cut into which carcasses and sides of meat are separated, such as a beef round, pork loin, lamb flank or veal breast.

"Public water system" has the meaning stated in 40 CFR 141 National Primary Drinking Water Regulations.

"Ready-to-eat food" means food that is in a form that is edible without washing, cooking, or additional preparation by the food establishment or the consumer and that is reasonably expected to be consumed in that form. Ready-to-eat food includes:

1. Potentially hazardous food that is unpackaged and cooked to the temperature and time required for the specific food under 12 VAC 5-421-700;

- 2. Raw, washed, cut fruits and vegetables;
- 3. Whole, raw, fruits and vegetables that are presented for consumption without the need for further washing, such as at a buffet; and
- 4. Other food presented for consumption for which further washing or cooking is not required and from which rinds, peels, husks, or shells are removed.

"Reduced oxygen packaging" means the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the surrounding 21% oxygen atmosphere, and a process as specified in this definition that involves a food for which Clostridium botulinum is identified as a microbiological hazard in the final packaged form.

"Refuse" means solid waste not carried by water through the sewage system.

"Regulatory authority" means the Virginia Department of Agriculture and Consumer Services, the Virginia Department of Health or their authorized representative having jurisdiction over the food establishment.

"Restricted use pesticide" means a pesticide product that contains the active ingredients specified in 40 CFR 152.175 Pesticides classified for restricted use, and that is limited to use by or under the direct supervision of a certified applicator.

"Safe material" means an article manufactured from or composed of materials that may not reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of any food; an additive that is used as specified in § 409 or 706 of the Federal Food, Drug, and Cosmetic Act; or other materials that are not additives and that are used in conformity with applicable regulations of the Food and Drug Administration.

"Sanitization" means the application of cumulative heat or chemicals on cleaned food contact surfaces that, when evaluated for efficacy, yield a reduction of 5 logs, which is equal to a 99.999% reduction, of representative disease microorganisms of public health importance.

"Sealed" means free of cracks or other openings that permit the entry or passage of moisture.

"Service animal" means an animal such as a guide dog, signal dog, or other animal individually trained to provide assistance to an individual with a disability.

"Servicing area" means an operating base location to which a mobile food establishment or transportation vehicle returns regularly for such things as vehicle and equipment cleaning, discharging liquid or solid wastes, refilling water tanks and ice bins, and food.

"Sewage" means liquid waste containing animal or vegetable matter in suspension or solution and may include liquids containing chemicals in solution.

"Shellfish control authority" means a state, federal, foreign, or other government entity legally responsible for administering a program that includes certification of molluscan shellfish harvesters and dealers for interstate commerce such as the Virginia Department of Health Bureau of Shellfish Sanitation.

"Shellstock" means raw, in-shell molluscan shellfish.

"Shucked shellfish" means molluscan shellfish that have one or both shells removed.

"Single-service articles" means tableware, carry-out utensils, and other items such as bags, containers, placemats, stirrers, straws, toothpicks, and wrappers that are designed and constructed for one time, one person use after which they are intended for discard.

"Single-use articles" means utensils and bulk food containers designed and constructed to be used once and discarded. Single-use articles includes items such as wax paper, butcher paper, plastic wrap, formed aluminum food containers, jars, plastic tubs or buckets, bread wrappers, pickle barrels, ketchup bottles, and number 10 cans which do not meet the materials, durability, strength and cleanability specifications contained in 12 VAC 5-421-960, 1080, and 1100 for multiuse utensils.

"Slacking" means the process of moderating the temperature of a food such as allowing a food to gradually increase from a temperature of -10° F (-23° C) to 25° F (-4° C) in preparation for deep-fat frying or to facilitate even heat penetration during the cooking of previously block-frozen food such as spinach.

"Smooth" means a food-contact surface having a surface free of pits and inclusions with a cleanability equal to or exceeding that of (100 grit) number 3 stainless steel; a nonfood-contact surface of equipment having a surface equal to that of commercial grade hot-rolled steel free of visible scale; and a floor, wall, or ceiling having an even or level surface with no roughness or projections that render it difficult to clean.

"Substantial compliance" shall mean that details of equipment or structure design or construction and/or food preparation, handling, storage, transportation and/or cleaning procedures will not substantially affect health consideration or performance of the facility or its employees.

"Table-mounted equipment" means equipment that is not easily moveable and is designed to be mounted off the floor on a table, counter, or shelf.

"Tableware" means eating, drinking, and serving utensils for table use such as flatware including forks, knives, and spoons; hollowware including bowls, cups, serving dishes, tumblers; and plates.

"Temperature measuring device" means a thermometer, thermocouple, thermistor, or other device that indicates the temperature of food, air, or water.

"Temporary food establishment" means a food establishment that operates for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

"USDA" means the U.S. Department of Agriculture.

"Utensil" means a food-contact implement or container used in the storage, preparation, transportation, dispensing, sale, or service of food, such as kitchenware or tableware that is multiuse, single-service, or single-use; gloves used in contact with food; food temperature measuring devices; and probe-type price or identification tags used in contact with food.

"Variance" means a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this Chapter if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver.

"Vending machine" means a self-service device that, upon insertion of a coin, paper currency, token, card, or key, or by optional manual operation, dispenses unit servings of food in bulk or in packages without the necessity of replenishing the device between each vending operation.

"Vending machine location" means the room, enclosure, space, or area where one or more vending machines are installed and operated and includes the storage and servicing areas on the premises that are used in conjunction with the vending machines.

"Warewashing" means the cleaning and sanitizing of food-contact surfaces of equipment and utensils.

"Whole-muscle, intact beef" means whole muscle beef that is not injected, mechanically tenderized, reconstructed, or scored and marinated, from which beef steaks may be cut.

Definitions and Purpose

Article 2

Purpose

12 VAC 5-421-20. Authority for regulation.

Sections 35.1-1 through 35.1-26 of the Code of Virginia address hotels, restaurants (hereinafter food establishments), summer camps and campgrounds. Those sections of these regulations provide that the State Board of Health has the duty to protect the public health and to ensure that in any place where food is prepared for service to the public, in any place where food is served, in any place or operation which prepares or stores food for distribution to persons of the same business operation or of a related business operation for service to the public, that said food is safely prepared, handled, protected and preserved. In order to discharge that duty, the board is empowered to supervise and regulate food at food establishments, within the state and to establish advisory standards for exempt entities. The board is also empowered to classify food establishments.

12 VAC 5-421-30. Purpose of regulation.

This part has been promulgated by the State Board of Health to specify the following requirements to protect public health:

- 1. A procedure for obtaining a license (permit);
- 2. Criteria for assuring the safe preparation, handling, protection and/or temperature control for food;
- 3. Criteria for the safe and sanitary maintenance, storage, operation and use of equipment;
- 4. Requirements that food establishments be connected to, and use an approved water supply and sewage disposal system;
- 5. Requirements for toilet and cleansing facilities for employees and customers;
- 6. Criteria for vector and pest control;
- 7. Requirements for the sanitary maintenance and use of food establishment's physical plant;

- 8. Requirements for appropriate lighting and ventilation not otherwise provided for in the Uniform Statewide Building Code; and
- 9. A classification system for food establishments.

12 VAC 5-421-40. Administration of regulation.

This chapter is administered by the following:

- 1. The State Board of Health, hereinafter referred to as the board, has responsibility to promulgate, amend and repeal regulations necessary to protect the public health.
- 2. The State Health Commissioner, hereinafter referred to as the commissioner, is the chief executive officer of the State Department of Health. The commissioner has the authority to act within the scope of regulations promulgated by the board and for the board when it is not in session.
- 3. The district or local health director, hereinafter referred to as the director, is responsible for the permitting and inspection of food establishments located within the director's district and for assuring compliance with this part. The director is the duly designated officer or agent of the commissioner.

Part II

Management and Personnel

Article 1

Supervision

The permit holder shall be the person in charge or shall designate a person in charge and shall ensure that a person in charge is present at the food establishment during all hours of operation.

Designation of a person in charge during all hours of operations ensures the continuous presence of someone who is responsible for monitoring and managing all food establishment operations and who is authorized to take actions to ensure that the Code's objectives are fulfilled. During the day-to-day operation of a food establishment, a person who is immediately available and knowledgeable in both operational and Code requirements is needed to respond to questions and concerns and to resolve problems.

12 VAC 5-421-60. Demonstration of Knowledge.*

2-102.11

Based on the risks of foodborne illness inherent to the food operation, during inspections and upon request the person in charge shall demonstrate to the regulatory authority knowledge of foodborne disease prevention, and the requirements of these regulations. The person in charge shall demonstrate this knowledge by being a certified food protection manager who has shown proficiency of required information through passing a test that is part of an accredited program, or by responding correctly to the environmental health specialist's questions as they relate to the specific food operation. The areas of knowledge may include:

- 1. Describing the relationship between the prevention of foodborne disease and the personal hygiene of a food employee;
- 2. Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a food employee who has a disease or medical condition that may cause foodborne disease;
- 3. Describing the symptoms associated with the diseases that are transmissible through food;
- 4. Explaining the significance of the relationship between maintaining the time and temperature of potentially hazardous food and the prevention of foodborne illness;
- 5. Explaining the hazards involved in the consumption of raw or undercooked meat, poultry, eggs, and fish;
- 6. Stating the required food temperatures and times for safe cooking of potentially hazardous food including meat, poultry, eggs, and fish;
- 7. Stating the required temperatures and times for the safe refrigerated storage, hot holding, cooling, and reheating of potentially hazardous food;

- 8. Describing the relationship between the prevention of foodborne illness and the management and control of the following:
 - a. Cross contamination,
 - b. Hand contact with ready-to-eat foods,
 - c. Handwashing, and
 - d. Maintaining the food establishment in a clean condition and in good repair;
- 9. Explaining the relationship between food safety and providing equipment that is:
 - a. Sufficient in number and capacity, and
 - b. Properly designed, constructed, located, installed, operated, maintained, and cleaned;
- 10. Explaining correct procedures for cleaning and sanitizing utensils and food-contact surfaces of equipment;
- 11. Identifying the source of water used and measures taken to ensure that it remains protected from contamination such as providing protection from backflow and precluding the creation of cross connections;
- 12. Identifying poisonous or toxic materials in the food establishment and the procedures necessary to ensure that they are safely stored, dispensed, used, and disposed of according to law;
- 13. Identifying control points in the operation from purchasing through sale or service that may contribute to the transmission of foodborne illness and explaining steps taken to ensure that the points are controlled in accordance with the requirements of this Chapter;
- 14. Explaining the details of how the person in charge and food employees comply with a HACCP plan if such a plan is a voluntary agreement between the regulatory authority and the establishment; and
- 15. Explaining the responsibilities, rights, and authorities assigned by this Chapter to the:
 - a. Food employee,

- b. Person in charge, and
- c. Regulatory authority.

The designated person in charge who is knowledgeable about foodborne disease prevention, Hazard Analysis and Critical Control Point (HACCP) principles, and Code requirements is prepared to recognize conditions that may contribute to foodborne illness or that otherwise fail to comply with Code requirements, and to take appropriate preventive and corrective actions.

There are many ways in which the person in charge can demonstrate competency. Many aspects of the food operation itself will reflect the competency of that person. A dialogue with the person in charge during the inspection process will also reveal whether or not that person is enabled by a clear understanding of the Code and its public health principles to follow sound food safety practices and to produce foods that are safe, wholesome, unadulterated, and accurately represented.

The effectiveness of the person in charge in protecting the health of the consumer is evidenced by the person's ability to apply the required knowledge to the establishment's operations by designing and implementing procedures that ensure continued compliance with the Code.

Status of "Universal Acceptance" of Food Protection Manager Certificates

Presently there are a wide variety of industry management training and certification programs being offered by regulatory agencies, academic institutions, food companies, industry groups and "third-party" organizations. Most certification programs share a common desire to have the food manager certificate they issue universally recognized and accepted by others - especially by the increasing number of regulatory authorities that require food manager certification.

Certification programs vary significantly in focus and primary mission of sponsors, organizational structures, staff resources, revenue sources, testing mechanisms, policies toward applicants and employers of food managers, and policies pertaining to such things as public information, criteria for maintaining certification, and the need for recertification. Where courses are offered, they vary in scope, content, depth and duration, quality of instructional materials, qualifications of instructors, and instructional approach (classroom, on-the-job, PC-based, home study, etc.). Where testing is a program component, varying degrees of attention are given to test construction and test administration as they relate to nationally accepted standards (reliability, validity, job analysis, subject weighting, cut scores, test security, etc.).

Needed is a mechanism for regulatory authorities to use in determining which certificates should be considered credible based on which certificate-issuing programs meet sound organizational and certification procedures and use defensible processes in their test development and test administration.

Considerable progress has been made by the Conference for Food Protection toward providing the standards and procedures necessary for the independent evaluation and accreditation of food protection manager certification programs. The Conference is simultaneously working on two separate aspects of the program accreditation process.

The first aspect addresses the important matter of ensuring that examinations are reliable, valid, and legally defensible. The Conference has developed a process for the independent evaluation and recognition of food protection manager certification examinations that meet its standards for test development and test administration. It is projected that this aspect of the process will be announced and become available to test providers in early 1999.

The second aspect addresses the equally important organizational and operational policies and procedures of a certification program that help ensure honesty and fairness for all stakeholders and protect against conflict of interests. The Conference is working closely with national organizations that have considerable experience with the accreditation of certification programs, and is endeavoring to develop a comparable process for evaluating these aspects of a certification program.

Once the Conference completes its work on these two program components, program accreditation may become the needed mechanism for promoting the universal acceptance of certificates issued by accredited certifiers.

12 VAC 5-421-70. Person in Charge.

2-103.11

The person in charge shall ensure that:

- 1. Food establishment operations are not conducted in a private home or in a room used as living or sleeping quarters as specified under 12 VAC 5-421-2990;
- 2. Persons unnecessary to the food establishment operation are not allowed in the food preparation, food storage, or warewashing areas, except that brief visits and tours may be authorized by the person in charge if steps are taken to ensure that exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles are protected from contamination
- 3. Employees and other persons such as delivery and maintenance persons and pesticide applicators entering the food preparation, food storage, and warewashing areas comply with these regulations;

- 4. Employees are effectively cleaning their hands, by routinely monitoring the employees' handwashing;
- 5. Employees are visibly observing foods as they are received to determine that they are from approved sources, delivered at the required temperatures, protected from contamination, unadulterated, and accurately presented, by routinely monitoring the employees' observations and periodically evaluating foods upon their receipt;
- 6. Employees are properly cooking potentially hazardous food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures;
- 7. Employees are using proper methods to rapidly cool potentially hazardous foods that are not held hot or are not for consumption within 4 hours, through daily oversight of the employees' routine monitoring of food temperatures during cooling;
- 8. Reserved;
- 9. Employees are properly sanitizing cleaned multiuse equipment and utensils before they are reused, through routine monitoring of solution temperature and exposure time for hot water sanitizing, and chemical concentration, pH, temperature, and exposure time for chemical sanitizing; and
- 10. Consumers are notified that clean tableware is to be used when they return to self-service areas such as salad bars and buffets; and
- 11. Employees are preventing cross-contamination of ready-to-eat food with bare hands by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; and
- 12. Employees are properly trained in food safety as it relates to their assigned duties.

A primary responsibility of the person in charge is to ensure compliance with Code requirements. Any individual present in areas of a food establishment where food and food-contact items are exposed presents a potential contamination risk. By controlling who is allowed in those areas and when visits are scheduled and by assuring that all authorized persons in the establishment, such as delivery, maintenance and service personnel, and pest control operators, comply with the Code requirements, the person in charge establishes an important barrier to food contamination.

Tours of food preparation areas serve educational and promotional purposes; however, the timing of such visits is critical to food safety. Tours may disrupt standard or routine operational procedures, and the disruption could lead to unsafe food. By scheduling tours during nonpeak hours the opportunities for contamination are reduced.

Part II

Management and Personnel

Article 2

Employee Health

12 VAC 5-421-80. Responsibility of the Person in Charge to Require Reporting by Food Employees and Applicants.* **2-201.11**

The permit holder shall require food employee applicants to whom a conditional offer of employment is made and food employees to report to the person in charge, information about their health and activities as they relate to diseases that are transmissible through food. A food employee or applicant shall report the information in a manner that allows the person in charge to prevent the likelihood of foodborne disease transmission, including the date of onset of jaundice or of an illness specified in Subsection A of this section, if the food employee or applicant:

- A. Is diagnosed with an illness due to:
 - 1. Salmonella typhi,
 - 2. Shigella spp.,
 - 3. Escherichia coli O157:H7, or
 - 4. Hepatitis A virus;
- B. Has a symptom caused by illness, infection, or other source that is:
 - 1. Associated with an acute gastrointestinal illness such as:
 - a. Diarrhea,

- b. Fever,
- c. Vomiting,
- d. Jaundice, or
- e. Sore throat with fever, or
- 2. A lesion containing pus such as a boil or infected wound that is open or draining and is:
 - a. On the hands or wrists, unless an impermeable cover such as a finger cot or stall protects the lesion and a single-use glove is worn over the impermeable cover,
 - b. On exposed portions of the arms, unless the lesion is protected by an impermeable cover, or
 - c. On other parts of the body, unless the lesion is covered by a dry, durable, tight-fitting bandage;
- C. Had a past illness from an infectious agent specified in Subsection A of this section; or
- D. Meets one or more of the following high-risk conditions:
 - 1. Is suspected of causing, or being exposed to, a confirmed disease outbreak caused by S. typhi, Shigella spp., E. coli O157:H7, or hepatitis A virus including an outbreak at an event such as a family meal, church supper, or festival because the food employee or applicant:
 - a. Prepared food implicated in the outbreak,
 - b. Consumed food implicated in the outbreak, or
 - c. Consumed food at the event prepared by a person who is infected or ill with the infectious agent that caused the outbreak or who is suspected of being a shedder of the infectious agent, or
 - 2. Lives in the same household as a person who is diagnosed with a disease caused by S. typhi, Shigella spp., E. coli O157:H7, or hepatitis A virus,

3. Lives in the same household as a person who attends or works in a setting where there is a confirmed disease outbreak caused by S. typhi, Shigella spp., E. coliO157:H7, or hepatitis A virus.

A wide range of communicable diseases and infections may be transmitted by infected food employees to consumers through food or food utensils. Proper management of a food establishment operation begins with employing healthy people and instituting a system of identifying employees who present a risk of transmitting foodborne pathogens to food or to other employees. In order to protect the health of both consumers and employees, information concerning the health status of applicants and food employees must be disclosed to the person in charge.

Title I of the Americans with Disabilities Act of 1990 (ADA) prohibits medical examinations and inquiries as to the existence, nature, or severity of a disability before extending a conditional offer of employment. In order for the permit holder and the person in charge to be in compliance with this particular aspect of the Code and the ADA, a conditional job offer must be made before making inquiries about the applicant's health status.

Furthermore, an applicant to whom an employment offer is conditionally made or a food employee who meets the Code conditions that require restriction from certain duties or exclusion must be accommodated to the extent provided under the ADA. That is, if there is an accommodation that will not pose an undue hardship and that will prevent the transmission of the disease(s) of concern through food, such accommodation, e.g., reassignment to duties that fulfill the intent of restriction or exclusion, must be made. It should be noted that the information provided here about the ADA is intended to alert employers to the existence of ADA and related CFR requirements. For a comprehensive understanding of the ADA and its implications, consult the references listed in the References Annex that relate to this section of the Code or contact the U. S. Equal Employment Opportunity Commission.

The information required from applicants and food employees is designed to identify employees who may be suffering from a disease which can be transmitted through food. It is the responsibility of the permit holder to convey to applicants and employees the importance of notifying the person in charge of changes in their health status. Once notified, the person in charge can take action to prevent the likelihood of the transmission of foodborne illness.

Applicants, to whom a conditional offer of employment is extended, and food employees are required to report specific high-risk conditions, medical symptoms, and previous illnesses. The symptoms listed may be indicative of a disease that is transmitted through the food supply by infected food employees. As required by the ADA, on August 15, 1996, the Centers for Disease Control and Prevention (CDC) published a list of infectious and communicable diseases that are transmitted through food. CDC updates the list annually. The list is divided into two parts:

pathogens often transmitted (List I) and pathogens occasionally transmitted (List II) through food by infected food employees.

The Lists below summarize the CDC list by comparing the common symptoms of each pathogen. Symptoms may include diarrhea, fever, vomiting, jaundice, and sore throat with fever. CDC has no evidence that the HIV virus is transmissible via food. Therefore, a food employee positive for the HIV virus is not of concern unless suffering secondary illness listed below.

LIST I. Pathogens Often Transmitted by Food Contaminated by Infected Employees.

	D	F	V	J	S
1. Hepatitis A virus	-	F	-	J	-
2. Salmonella Typhi	-	\boldsymbol{F}	-	-	-
3. Shigella species	D	\boldsymbol{F}	V	-	-
4. Norwalk and Norwalk-like viruses	D	\boldsymbol{F}	V	-	-
5. Staphylococcus aureus	D	-	V	-	-
6. Streptococcus pyogenes -		F	-	-	S
LIST II. Pathogens Occasionally Transmitted by Food C Infected Employees	Contamin	atec	l by		
	D	F	V	J	S
1. Campylobacter jejuni	D	F	V	-	-
2. Entamoeba histolytica	D	$\boldsymbol{\mathit{F}}$	-	-	-
3. Enterohemorrhagic Escherichia coli	D	-	-	-	-
4. Enterotoxigenic Escherichia coli	D	-	V	-	-
5. Giardia lamblia	D	-	-	-	-
6. Non-typhoidal Salmonella	D	F	V	-	-
7. Rotavirus	D	F	V	-	-
8. Taenia solium	-	-	-	-	-
9. Vibrio cholerae 01	D	-	V	-	-
10. Yersinia enterocolitica	D	\boldsymbol{F}	V	-	-

KEY: D = Diarrhea V = Vomiting S = Sore throat with fever <math>F = Fever J = Jaundice

The symptoms listed in the Code cover the common symptoms experienced by persons suffering from the pathogens identified by CDC as transmissible through food by infected food employees. An employee suffering from any of the symptoms listed presents an increased risk of transmitting foodborne illness.

The high-risk conditions that require reporting are designed to be used with the symptoms listed to identify employees who may be suffering from an illness due to the following pathogens: Salmonella Typhi, Shigella spp., Escherichia coli O157:H7, and hepatitis A virus. The specific conditions requiring reporting were identified by CDC as significant contributing factors to the incidence of foodborne illness.

The 4 organisms listed have been designated by CDC as having high infectivity. This designation is based on the number of confirmed cases reported that involved food employees infected with one of these organisms and the severity of the medical consequences to those who become ill.

Lesions containing pus that may occur on a food employee's hands, as opposed to such wounds on other parts of the body, represent a direct threat for introducing Staphylococcus aureus into food. Consequently, a double barrier is required to cover hand and wrist lesions. Pustular lesions on the arms are less of a concern when usual food preparation practices are employed and, therefore, a single barrier is allowed. However, if the food preparation practices entail contact of the exposed portion of the arm with food, a barrier equivalent to that required for the hands and wrists would be necessitated. Lesions on other parts of the body need to be covered; but, an impermeable bandage is not considered necessary for food safety purposes. Food employees should be aware that hands and fingers that contact pustular lesions on other parts of the body or with the mucous membrane of the nose also pose a direct threat for introducing Staphylococcus aureus into food.

12 VAC 5-421-90. Exclusions and Restrictions.*

2-201.12

The person in charge shall:

- 1. Exclude a food employee from a food establishment if the food employee is diagnosed with an infectious agent specified in 12 VAC 5-421-80 A;
- 2. Except as specified under Subsection C or D of this section, restrict a food employee from working with exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles, in a food establishment if the food employee is:
 - a. Suffering from a symptom specified in 12 VAC 5-421-80 B, or
 - b. Not experiencing a symptom of acute gastroenteritis specified in subsection 12 VAC 5-421-80 B 1 but has a stool that yields a specimen culture that is positive for Salmonella typhi, Shigella spp., or E. coli O157:H7;
- 3. If the population served is a highly susceptible population, exclude a food employee who:

- a. Is experiencing a symptom of acute gastrointestinal illness specified in subsection 12 VAC 5-421-80 B 1 and meets a high-risk condition specified in subsections 12 VAC 5-421-80 D 1 through 4 3.
- b. Is not experiencing a symptom of acute gastroenteritis specified in subsection 12 VAC 5-421-80 B 1 but has a stool that yields a specimen culture that is positive for S. typhi, Shigella spp., or E. coli O157:H7,
- c. Had a past illness from S. typhi within the last 3 months, or
- d. Had a past illness from Shigella spp. or E. coli O157:H7 within the last month; and
- 4. For a food employee who is jaundiced:
 - a. If the onset of jaundice occurred within the last 7 calendar days, exclude the food employee from the food establishment, or
 - b. If the onset of jaundice occurred more than 7 calendar days before:
 - (1) Exclude the food employee from a food establishment that serves a highly susceptible population, or
 - (2) Restrict the food employee from activities specified in 12 VAC 5-421-90 2, if the food establishment does not serve a highly susceptible population.

Restriction or exclusion of food employees suffering from a disease or medical symptom listed in the Code is necessary due to the increased risk that the food being prepared will be contaminated with a pathogenic organism transmissible through food. A person suffering from any of the symptoms or medical conditions listed may be suffering from a disease transmissible through food.

Because of the high infectivity (ability to invade and multiply) and virulence (ability to produce severe disease) of Salmonella Typhi, Shigella spp., Escherichia coli O157:H7, and hepatitis A virus, a food employee diagnosed with an active case of illness caused by any of these four pathogens must be excluded from food establishments. The exclusion is based on the severe medical consequences to individuals infected with these organisms, i.e., hospitalization and even death.

Restrictions and exclusions vary according to the population served because highly susceptible populations have increased vulnerability to foodborne illness. For example, foodborne illness in a healthy individual may be manifested by mild flu-like symptoms. The same foodborne illness

may have serious medical consequences in immunocompromised individuals. This point is reinforced by statistics pertaining to deaths associated with foodborne illness caused by **Salmonella Enteritidis**. Over 70% of the deaths attributed to this organism occurred among individuals who for one reason or another were immunocompromised. This is why the restrictions and exclusions listed in the Code are especially stringent for food employees serving highly susceptible populations.

The symptoms experienced by individuals infected with **Salmonella Typhi, Shigella** spp., **Escherichia coli** O157:H7, or hepatitis A virus are often severe and of sufficient duration that most employees will seek medical assistance. The Code provisions related to individuals who encounter any of the high-risk conditions listed and also suffer from any of the symptoms listed in the Code are designed to identify individuals who are likely to be suffering from an illness caused by 1 of the 4 organisms that requires exclusion.

Periodic testing of food employees for the presence of diseases transmissible through food is not cost effective or reliable. Therefore, restriction and exclusion provisions are triggered by the active symptoms and high-risk conditions listed. A high-risk condition alone does not trigger restriction or exclusion. The employee must also suffer from one of the symptoms listed.

The use of high-risk conditions alone as the sole basis for restricting or excluding food employees is difficult to justify. The high-risk conditions that must be reported apply only to the 4 organisms listed. Of the 4 organisms listed, hepatitis A presents a different twist to this rationale. Food employees who meet a high-risk condition involving hepatitis A may shed the virus before becoming symptomatic. In fact, the infected employee could be shedding hepatitis A virus for up to a week before experiencing symptoms of the infection. However, even in light of this fact, blanket exclusion or restriction of a food employee solely because of a high-risk condition involving hepatitis A is not justified.

The following summarize the rationale for not restricting or excluding an asymptomatic food employee simply because the employee meets a high-risk condition involving hepatitis A:

- 1. Because hepatitis A virus infection can occur without clinical illness (i.e., without symptoms), or because a person may shed hepatitis A virus in the stool for up to a week before becoming symptomatic, it is possible that a person unknowingly may have been exposed to an asymptomatic hepatitis A virus shedder or to an infected person who is in the incubation stage. No restriction/exclusion routinely occurs under these -- presumably much more common -- circumstances.
- 2. Even though the asymptomatic food employee may be infected with hepatitis A virus and may in fact be shedding virus in the stool, foodborne transmission of hepatitis A virus is unlikely if the employee practices good personal hygiene, such as washing hands after going to the bathroom.
- 3. Exclusions from work for prolonged periods of time may involve economic hardship for the food employee excluded.

Based on the information presented, exclusion or restriction solely on a high-risk condition would be potentially controversial and of questionable merit.

Because of the high infectivity of hepatitis A, the person in charge or regulatory authority should handle employees and applicants who meet a high-risk condition involving hepatitis A on a case-by-case basis. With this approach in mind, the following criteria are offered as a guide. First, the following information should be collected and analyzed:

- 1. Clarify the type of contact the individual had with another person diagnosed with hepatitis A virus infection. Keep in mind that the closer the contact (i.e., living in the same household as the infected person), the more likely it is that a susceptible person may become infected.
- 2. What job does the food employee perform at the food establishment, e.g., is the employee involved in food preparation?
- 3. When did the employee begin work at the establishment?
- 4. What level of personal hygiene does the individual exhibit? For example, does the individual adhere to the handwashing requirements specified in the Code?
- 5. Has the individual suffered from hepatitis A in the past? If the answer to this question is yes, was blood testing done? If the individual did have hepatitis A in the past, the individual is immune from re-infection.
- 6. In terms of the current high-risk condition, has the individual received immune globin (IG)? When?

In addition, upon being notified of the high-risk condition, the person in charge should immediately:

- 1. Discuss the traditional modes of transmission of hepatitis A virus infection with the food employee involved.
- 2. Advise the food employee to observe good hygienic practices both at home and at work. This includes a discussion of proper handwashing, as described in the Code, after going to the bathroom, changing diapers, or handling stool-soiled material.
- 3. Review the symptoms listed in the Code that are caused by hepatitis A infection.
- 4. Remind the employee of the employee's responsibility as specified in the Code to inform the person in charge immediately upon the onset of any of the symptoms listed in the Code.

5. In light of the high infectivity of hepatitis A, ensure that the employee stops work immediately if any of the symptoms described in the Code develop and reports to the person in charge.

If after consideration of all the information gathered, the person in charge feels that the employee in question is likely to develop hepatitis A, restriction or exclusion of the individual's activities should be considered.

12 VAC 5-421-100. Removal of Exclusions and Restrictions.

2-201.13

- A. The person in charge may remove an exclusion specified under 12 VAC 5-421-90 1 if:
 - 1. The person in charge obtains approval from the regulatory authority; and,
 - 2. The person excluded as specified under 12 VAC 5-421-90 1 provides to the person in charge written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, that specifies that the excluded person may work in an unrestricted capacity in a food establishment, including an establishment that serves a highly susceptible population, because the person is free of the infectious agent of concern as specified in 12 VAC 5-421-4070.
- B. The person in charge may remove a restriction specified under:
 - 1. Subsection 12 VAC 5-421-90 2 a if the restricted person:
 - a. Is free of the symptoms specified under 12 VAC 5-421-80 B and no foodborne illness occurs that may have been caused by the restricted person,
 - b. Is suspected of causing foodborne illness but:
 - (1) Is free of the symptoms specified under 12 VAC 5-421-80 B, and
 - (2) Provides written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, stating that the restricted person is free of the infectious agent that is suspected of causing the person's symptoms or causing foodborne illness, as specified in 12 VAC 5-421-4070, or
 - c. Provides written medical documentation from a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis; or

- 2. Subsection 12 VAC 5-421-90 2 b if the restricted person provides written medical documentation from a physician, licensed to practice medicine, or, if allowed by law, a nurse practitioner or physician assistant, according to the criteria specified in 12 VAC 5-421-4070 that indicates the stools are free of Salmonella typhi, Shigella spp., or E. coli O157:H7, whichever is the infectious agent of concern.
- C. The person in charge may remove an exclusion specified under 12 VAC 5-421-90 3 if the excluded person provides written medical documentation from a physician licensed to practice medicine:
 - 1. That specifies that the person is free of:
 - a. The infectious agent of concern as specified in 12 VAC 5-421-4070, or
 - b. Jaundice as specified under 12 VAC 5-421-100 D if hepatitis A virus is the infectious agent of concern; or,
 - 2. If the person is excluded under 12 VAC 5-421-90 3 a, stating that the symptoms experienced result from a chronic noninfectious condition such as Crohn's disease, irritable bowel syndrome, or ulcerative colitis.
- D. The person in charge may remove an exclusion specified under subsection 12 VAC 5-421-90 4 a and subsection 12 VAC 5-421-90 4 b a and a restriction specified in subsection 12 VAC 5-421-90 4 b (2) if:
 - 1. No foodborne illness occurs that may have been caused by the excluded or restricted person and the person provides written medical documentation from a physician licensed to practice medicine stating that specifies that the person is free of hepatitis a virus as specified in subsection 12 VAC 5-421-4070 4 a; or
 - 2. The excluded or restricted person is suspected of causing foodborne illness and complies with subsections 12 VAC 5-421-4070 4 a and 4 b.

Chapter 2 provisions related to employee health are structured to recognize certain characteristics of each of the four infectious agents, the risk of illness presented by asymptomatic shedders, the increased risk to highly susceptible populations, and the need to provide extra protection to those high-risk populations.

Asymptomatic shedders are food employees who do not exhibit the symptoms of foodborne illness but who are identified through laboratory analysis of their stools to have any one of the three bacterial pathogens identified in Chapter 2 in their gastrointestinal system.

The duties that an asymptomatic shedder performs in a food establishment are restricted if the establishment serves a general population or, if a highly susceptible population is involved, the shedder is excluded. Several considerations factor into the need to preclude asymptomatic shedders from food establishment functions that may result in the transmission of foodborne disease.

Outbreaks of foodborne illness involving **Salmonella Typhi** have been traced to asymptomatic food employees who have transmitted the pathogen to food, causing illness.

There is some epidemiological evidence of transmission of food via food employees infected with **Shigella** spp.

Healthy consumers are at risk due to a low infectious dose of **Shigella** spp.

Despite lacking epidemiological evidence of transmission of food via food employees infected with **E. coli** O157:H7, the documented ease of transmitting it from person-to-person in a day care setting, suggests a low infectious dose and the potential for the organism to be transmitted through food.

The severity and consequences of one of the illnesses, Hemolytic Uremic Syndrome (HUS), associated with **E. coli** O157:H7 warrant the institution of disease interventions.

Restriction in a food establishment that does not serve a highly susceptible population affords protection for the general population and the immune-suppressed subset of the general population.

The risk that a communicable disease will be transmitted by food employees who are asymptomatic shedders varies depending upon the hygienic habits of the worker, the food itself and how it is prepared, the susceptibility of the population served, and the infectivity of the organism.

To minimize the risk in all food establishments of the transmission of foodborne disease by an asymptomatic shedder and based on the factors listed above, all known asymptomatic shedders of the three bacterial pathogens are either restricted or excluded, depending on the population served. Requiring restriction for asymptomatic shedders of all three of the bacterial pathogens results in a uniform criterion and is consistent with APHA-published recommendations in the "Control of Communicable Diseases in Man."

The Code requires medical clearance, based on criteria designed to detect the shedder state, before a person who had a recent illness from, or is identified as a shedder of any of the three bacterial infectious agents is allowed to resume the duties from which that person was restricted or, in the case of an establishment that serves a highly susceptible population, before the person may return to work.

With respect to a food employee in an establishment that serves an immunocompromised population, the Code provisions are more stringent in that <u>exclusion</u> is required in 3 situations in which it is not required for food employees in other food establishments. Those 3 situations involve an employee who:

- (A) Meets a high-risk condition specified in \P 12 VAC 5-421-80(D) and has a symptom of acute gastrointestinal illness;
- (B) Is diagnosed as an asymptomatic shedder of **S. Typhi**, **Shigella** spp. or **Escherichia coli** 0157:H7; or
- (C) Had a recent illness caused by **S. Typhi, Shigella** spp., or **E. coli** O157:H7. The exclusion is in effect until a physician licensed to practice medicine or, if allowed by law, a nurse practitioner or physician assistant, provides the medical clearance specifically outlined in § 12 VAC 5-421-4070 of the Code, indicating that the infectious agent is not detected.

12 VAC 5-421-110. Responsibility of a Food Employee or an Applicant to Report to the Person in Charge.*

A food employee or a person who applies for a job as a food employee shall:

- 1. In a manner specified in 12 VAC 5-421-80, report to the person in charge the information specified in 12 VAC 5-421-80 A through D; and
- 2. Comply with exclusions and restrictions that are specified in 12 VAC 5-421-90 A through D.

This reporting requirement is an important component of any food safety program. A food employee who suffers from any of the illnesses or medical symptoms or meets any of the high-risk conditions in this Code may transmit disease through the food being prepared. The person in charge must first be aware that an employee or prospective employee is suffering from a disease or symptom listed in the Code before steps can be taken to reduce the chance of foodborne illness.

Some of the symptoms that must be reported may be observed by the person in charge. However, food employees and applicants share a responsibility for preventing foodborne illness and are obligated to inform the person in charge if they are suffering from any of the symptoms, high-risk conditions, or medical diagnoses listed in the Code and food employees must comply with restrictions or exclusions imposed upon them.

12 VAC 5-421-120. Reporting by the Person in Charge.*

2-201.15

The person in charge shall notify the regulatory authority that a food employee is diagnosed with an illness due to, Salmonella typhi, Shigella spp., Escherichia coli O157:H7, or hepatitis A virus.

Notification of the regulatory authority by the person in charge that an employee is suffering illness caused by **Salmonella Typhi**, **Shigella** spp., **Escherichia coli** O157:H7, or hepatitis A virus allows the regulatory authority to monitor for any associated cases of foodborne illness. The person in charge should be aware of the confidentiality provisions of the Americans with Disabilities Act (ADA). For information about the ADA, call 800-669-EEOC or for telecommunications device for the deaf (TDD) 800-800-3302.

Part II

Management and Personnel

Article 3

Personal Cleanliness

12 VAC 5-421-130. Clean Condition of Hands and Arms.*

2-301.11

Food employees shall keep their hands and exposed portions of their arms clean.

The hands are particularly important in transmitting foodborne pathogens. Food employees with dirty hands and/or fingernails may contaminate the food being prepared. Therefore, any activity which may contaminate the hands must be followed by thorough handwashing in accordance with the procedures outlined in the Code.

Even seemingly healthy employees may serve as reservoirs for pathogenic microorganisms that are transmissible through food. Staphylococci, for example, can be found on the skin and in the mouth, throat, and nose of many employees. The hands of employees can be contaminated by touching their nose or other body parts.

A. Except as specified in subsection B of this section, food employees shall clean their hands and exposed portions of their arms with a cleaning compound in a lavatory that is equipped as specified under 12 VAC 5-421-2190 A by vigorously rubbing together the surfaces of their lathered hands and arms for at least 20 seconds and thoroughly rinsing with clean, running water. Employees shall pay particular attention to the areas underneath the fingernails and between the fingers.

B. If approved and capable of removing the types of soils encountered in the food operations involved, an automatic handwashing facility may be used by food employees to clean their hands.

Many employees fail to wash their hands as often as necessary and even those who do may use a flawed technique. It takes more than just the use of soap and running water to remove the transient pathogens that may be present. It is the abrasive action obtained by vigorously rubbing the surfaces being cleaned that loosens the dirt or soil present.

Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Proper handwashing by employees after defecation establishes a protective barrier against the transmission of pathogens that may be present in the feces.

Pathogens transmissible through food may also be present in other body fluids. Therefore, precautions would be appropriate whenever an employee handles body fluids or body wastes directly or indirectly, because of the increased risk of the presence of disease. Fecal material and other contaminants routinely accumulate under the fingernails; therefore, particular attention must be given to the fingernails, fingertips, and areas between the fingers. Once the material and soil are loosened, they can be washed away in the rinsing step of proper handwashing.

This section is reserved.

In earlier editions of the Code, FDA's model contained a provision for a Special Procedure in certain situations. Pursuant to a 1996 Conference for Food Protection (CFP) Recommendation, the text of this Code provision is removed and the section is reserved. It is FDA's intent to further research the matter and to submit the findings to the CFP for reconsideration of the matter.

12 VAC 5-421-160. When to Wash.*

2-301.14

Food employees shall clean their hands and exposed portions of their arms as specified under 12 VAC 5-421-140 immediately before engaging in food preparation including working with exposed food, clean equipment and utensils, and unwrapped single-service and single-use articles and:

- 1. After touching bare human body parts or hair other than clean hands and clean, exposed portions of arms;
- 2. After using the toilet room;
- 3. After caring for or handling support animals as allowed under 12 VAC 5-421-250 B;
- 4. Except as specified in 12 VAC 5-421-220 B, after coughing, sneezing, using a handkerchief or disposable tissue, using tobacco, eating, or drinking;
- 5. After handling soiled equipment or utensils;
- 6. During food preparation, as often as necessary to remove soil and contamination and to prevent cross contamination when changing tasks;
- 7. When switching between working with raw foods and working with ready-to-eat foods;
- 8. Prior to donning single-use gloves if gloves are used; and,
- 9. After engaging in other activities that contaminate the hands.

The hands may become contaminated when the food employee engages in specific activities. The increased risk of contamination requires handwashing immediately after the activities listed. The specific examples listed in this Code section are not intended to be all inclusive. Employees must wash their hands after any activity which may result in contamination of the hands.

Food employees shall clean their hands in a handwashing lavatory and may not clean their hands in a sink used for food preparation or utensil washing.

Effective handwashing is essential for minimizing the likelihood of the hands becoming a vehicle of cross contamination. It is important that handwashing be done only at a properly equipped handwashing facility in order to help ensure that food employees effectively clean their hands. Handwashing facilities are to be conveniently located, always accessible for handwashing, maintained so they provide proper water temperatures and pressure, and equipped with suitable hand cleansers, nail brushes, and disposable towels and waste containers, or hand dryers. It is inappropriate to wash hands in a food preparation sink since this may result in avoidable contamination of the sink and the food prepared therein.

12 VAC 5-421-180. Hand Sanitizers

2-301.16

- A. A hand sanitizer and chemical hand sanitizing solution used as a hand dip shall:
 - 1. Comply with one of the following:
 - a. Be an approved drug that is listed in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations as an approved drug based on safety and effectiveness; or
 - b. Have active antimicrobial ingredients that are listed in:
 - (1) The FDA monograph for OTC Health-Care Antiseptic Drug Products as an antiseptic handwash, or
 - (2) The USDA List of Proprietary Substances and Nonfood Compounds, Miscellaneous Publication No. 1419; and
 - 2. Comply with one of the following:
 - a. Have components that are exempted from the requirement of being listed in federal Food Additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; or
 - b. Comply with and be listed in:
 - (1) 21 CFR 178-Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers as regulated for use as a Food Additive with condition of safe use, or

- (2) 21 CFR 182-Substances Generally Recognized as Safe, 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe, of 21 CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe for use in contact with Food; and
- 3. Be applied only to hands that are cleaned as specified under 12 VAC 5-421-140;
- B. If a hand sanitizer or a chemical hand sanitizing solution used as a hand dip does not meet the criteria specified under subsection A 2 of this section, use shall be:
 - 1. Followed by thorough hand rinsing in clean water before hand contact with food or by the use of gloves; or
 - 2. Limited to situations that involve no direct contact with food by the bare hands.
- C. A chemical hand sanitizing solution used as a hand dip shall be maintained clean and at a strength equivalent to 100 ppm(mg/l) chlorine or above.

This provision is intended to ensure that an antimicrobial product applied to the hands is both, 1) safe and effective when applied to human skin, and 2) a safe food additive when applied to bare hands that will come into direct contact with food. The prohibition against bare hand contact contained in \P 12 VAC 5-421-450(B) applies only to an exposed ready-to-eat food.

As a Drug Product

There are three means by which a hand sanitizer is considered to be safe and effective when applied to human skin:

1. A hand sanitizer may be approved by FDA under a new drug application based on data showing safety and effectiveness and may be listed in the publication Approved Drug Products with Therapeutic Equivalence Evaluations. Also known as the "Orange Book," this document provides "product-specific" listings rather than listings by compound. It is published annually with monthly supplements. These publications are available on the Internet via the FDA Web Site and Center for Drug Evaluation and Research Home Page, from the Superintendent of Documents/Government Printing Office, and from the National Technical Information Service. However, as of the end of 1998, no hand sanitizers are listed in this publication since no new drug applications have been submitted and approved for these products.

2. A hand sanitizer active ingredient may be identified by FDA in the monograph for OTC (over-the-counter) Health-Care Antiseptic Drug Products under the antiseptic handwash category. Since hand sanitizing products are intended and labeled for topical antimicrobial use by food employees in the prevention of disease in humans, these products are "drugs" under the Federal Food, Drug, and Cosmetic Act § 201(g). As drugs, hand sanitizers and dips must be manufactured by an establishment that is duly registered with the FDA as a drug manufacturer; their manufacturing, processing, packaging, and labeling must be performed in conformance with drug Good Manufacturing Practices (GMP's); and the product must be listed with FDA as a drug product.

Products having the same formulation, labeling, and dosage form as those that existed in the marketplace on or before December 4, 1975 or that are authorized by USDA are being evaluated under the OTC (over-the-counter) Drug Review by FDA's Center for Drug Evaluation and Research. Otherwise, the far more extensive FDA review process for a new drug application (NDA) is required before marketing.

However, as of the end of 1998, no hand sanitizers have been shown to be acceptable through this process since the monograph has not been finalized. FDA's Center for Drug Evaluation and Research is not presently objecting to the use of "instant hand sanitizers" based on ethyl alcohol or isopropyl alcohol, or certain chlorine "hand sanitizing dips" since these compounds are included in the OTC Drug Review. The ultimate status of these products will not be known until the final monograph publishes.

Acceptable antimicrobial ingredients for hand sanitizers will be identified in a future final monograph issued under the OTC Drug Review for OTC Antiseptic Handwashes. Information about whether a specific product has been accepted and included in the proposed monograph may be obtained from the manufacturer. You may also refer to Federal Register (59) No. 116, June 17, 1994, Tentative Final Monograph (TFM) for Health Care Antiseptic Drug Products; Proposed Rule. This TFM describes the inclusion of hand sanitizers in this Review, on page 31440 under Comment 28 of Part II.

- 3. A hand sanitizer may be previously authorized and listed for such use in the **USDA List** of **Proprietary Substances and Nonfood Compounds**, Miscellaneous Publication No. 1419. In this publication, Category Code Letter "E" covers Employee Hand Care products.
 - E-1 products are hand cleaners that require a potable water rinse.
 - E-2 products are hand cleaners that provide an antimicrobial equivalency of 50 ppm chlorine that require a potable water rinse.
 - E-3 products are hand sanitizers and hand sanitizer dips with 50 ppm chlorine equivalency that specify prior handwashing/rinsing. Hands need not be rinsed with potable water following use.

• E-4 products include products such as creams, lotions, or aerosol foams. Any such products intended to leave a film/shield on the skin to protect against contamination by chemicals, allergens, or microorganisms have been restricted by USDA to dressing and toilet rooms for use only when the food employee is leaving the plant. Since 1992, USDA has deferred to FDA with respect to E-4 barrier-type products and requires that manufacturers obtain FDA approval prior to any new USDA listing.

This USDA publication lists acceptable employee hand-care products in all four categories. The USDA review is based only on the intended uses specified for the product by the manufacturer in a written application. However, during the second half of 1998, USDA discontinued this review program and listing. It is unknown at this time whether another organization will assume some or all of these review and listing responsibilities.

Products in all four of these USDA listed hand-care product categories are regulated by FDA's Center for Drug Evaluation and Research. Questions regarding acceptability of a hand sanitizer with respect to OTC compliance may be directed to the OTC Compliance Team, HFD-312, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, Center for Drug Evaluation and Research, 7520 Standish Place, Rockville, MD 20855-2737. Specific product label/promotional information and the formulation are required for determining a product's regulatory status.

As a Food Additive

To be regulated under the food additive provisions of the Federal Food, Drug, and Cosmetic Act, the components of a hand-care product must reasonably be expected to become a component of food based upon the product's intended use. E-3 formulations in USDA's E-Classification system meet this criterion.

Where the components of a product are reasonably expected to become a component of food based upon the product's intended use, there are three means by which they are considered by FDA to be safe:

1. A substance may be exempted from the requirement of being listed in the federal food additive regulations as specified in 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles. A review by FDA's Center for Food Safety and Applied Nutrition is required for such an exemption to be issued. The Center's Indirect Additives Team has exempted ethyl alcohol and isopropyl alcohol from the requirement of being listed in the federal food additive regulations. Therefore, there is no food additive prohibition against using these substances as components of an instant hand sanitizer.

- 2. A substance may be regulated for the intended use as a food additive as specified in 21 CFR 178 Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers, and listed thereunder with conditions of safe use. However, as of 1998, no petitions have been received for the review and approval of substances for use as hand sanitizers, and therefore none are listed.
- 3. A substance may be "generally recognized as safe (GRAS)" for the intended use in contact with food within the meaning of the Federal Food, Drug, and Cosmetic Act § 201(s). Substances affirmed by FDA to be GRAS are listed in one of the following: 21 CFR 182 Substances Generally Recognized as Safe, 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe, or 21 CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe. The law also provides for independent GRAS determinations.

Only USDA's E-3 category products are regulated by FDA's Center for Food Safety and Applied Nutrition. The Indirect Additives Team does not certify or provide approvals for specific products. However, if the use of a product meets the regulations of 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles, FDA may provide a letter to a firm stating that the use of this product is exempt from the requirement of a food additive listing regulation. However, the product must be the subject of a new drug application or under FDA's OTC Drug Review to be legally marketed.

Questions regarding the regulatory status of hand sanitizer components as food additives may be directed to the Indirect Additives Team, HFS-215, Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 200 C Street, SW, Washington, DC 20204. It may be helpful or necessary to provide label/promotional information when inquiring about a specific component.

12 VAC 5-421-190. Maintenance of Fingernails.

2-302.11

Food employees shall keep their fingernails trimmed, filed, and maintained so the edges and surfaces are cleanable and not rough. While preparing food, food employees may not wear artificial fingernails or fingernail decorations other than nail polish.

The requirement for fingernails to be trimmed, filed, and maintained is designed to address both the cleanability of areas beneath the fingernails and the possibility that fingernails or pieces of the fingernails may end up in the food due to breakage. Failure to remove fecal material from beneath the fingernails after defecation can be a major source of pathogenic organisms. Ragged fingernails present cleanability concerns and may harbor pathogenic organisms.

12 VAC 5-421-200. Prohibition of Jewelry.

2-303.11

While preparing food, food employees may not wear jewelry on their arms and hands. This section does not apply to a plain ring such as a wedding band.

Items of jewelry such as rings, bracelets, and watches may collect soil and the construction of the jewelry may hinder routine cleaning. As a result, the jewelry may act as a reservoir of pathogenic organisms transmissible through food.

An additional hazard associated with jewelry is the possibility that pieces of the item or the whole item itself may fall into the food being prepared. Hard foreign objects in food may cause medical problems for consumers, such as chipped and/or broken teeth and internal cuts and lesions.

12 VAC 5-421-210. Clean Condition of Outer Clothing.

2-304.11

Food employees shall wear clean outer clothing to prevent contamination of food equipment, utensils, linens, and single-service and single-use articles.

Dirty clothing may harbor diseases that are transmissible through food. Food employees who inadvertently touch their dirty clothing may contaminate their hands. This could result in contamination of the food being prepared. Food may also be contaminated through direct contact with dirty clothing. In addition, employees wearing dirty clothes send a negative message to consumers about the level of sanitation in the establishment.

Part II

Management and Personnel

Article 4

Hygienic Practices

12 VAC 5-421-220. Eating, Drinking, or Using Tobacco.*

2-401.11

A. Except as specified in Subsection b of this section, an employee shall eat, drink, or use any form of tobacco only in designated areas where the contamination of exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; or other items needing protection can not result.

- B. A food employee may drink from a closed beverage container with a straw if the container is handled to prevent contamination of:
 - 1. The employee's hands;
 - 2. The container; and
 - 3. Exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

Proper hygienic practices must be followed by food employees in performing assigned duties to ensure the safety of the food, prevent the introduction of foreign objects into the food, and minimize the possibility of transmitting disease through food. Smoking or eating by employees in food preparation areas is prohibited because of the potential that the hands, food, and food-contact surfaces may become contaminated. Insanitary personal practices such as scratching the head, placing the fingers in or about the mouth or nose, and indiscriminate and uncovered sneezing or coughing may result in food contamination. Poor hygienic practices by employees may also adversely affect consumer confidence in the establishment.

Food preparation areas such as hot grills may have elevated temperatures and the excessive heat in these areas may present a medical risk to the workers as a result of dehydration. Consequently, in these areas food employees are allowed to drink from closed containers that are carefully handled.

12 VAC 5-421-230. Discharges from the Eyes, Nose, and Mouth.* 2-401.12

Food employees experiencing persistent sneezing, coughing, or a runny nose that causes discharges from the eyes, nose, or mouth may not work with exposed food; clean equipment, utensils, and linens; or unwrapped single-service or single-use articles.

Discharges from the eyes, nose, or mouth through persistent sneezing or coughing by food employees can directly contaminate exposed food, equipment, utensils, linens, and single-service and single-use articles. When these poor hygienic practices cannot be controlled, the employee must be assigned to duties that minimize the potential for contaminating food and surrounding surfaces and objects.

12 VAC 5-421-240. Effectiveness of Hair Restraints.

2-402.11

A. Except as provided under Subsection B of this section, food employees shall wear hair restraints such as hats, hair coverings or nets, beard restraints, and clothing that covers body hair, that

are designed and worn to effectively keep their hair from contacting exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

B. This section does not apply to food employees such as counter staff who only serve beverages and wrapped or packaged foods, hostesses, and wait staff if they present a minimal risk of contaminating exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

Consumers are particularly sensitive to food contaminated by hair. Hair can be both a direct and indirect vehicle of contamination. Food employees may contaminate their hands when they touch their hair. A hair restraint keeps dislodged hair from ending up in the food and may deter employees from touching their hair.

12 VAC 5-421-250. Handling of Animals Prohibited.*

2-403.11

A. Except as specified in Subsection B of this section, food employees may not care for or handle animals that may be present such as patrol dogs, support animals, or pets that are allowed under subsections 12 VAC 5-421-3310 B 2 through 4.

B. Food employees with support animals may handle or care for their support animals and food employees may handle or care for fish in aquariums or molluscan shellfish or crustacea in display tanks if they wash their hands as specified under 12 VAC 5-421-140 and 12 VAC 5-421-160 C.

Dogs and other animals, like humans, may harbor pathogens that are transmissible through food. Handling or caring for animals that may be legally present is prohibited because of the risk of contamination of food employee hands and clothing.

Part III

Food

Article 1

Characteristics

12 VAC 5-421-260. Safe and Unadulterated.*

3-101.11

Food shall be safe and unadulterated.

Part III

Food

Article 2

Sources, Specifications, and Original Containers and Records

12 VAC 5-421-270. Compliance with Food Law.*

3-201.11

- A. Food shall be obtained from sources that comply with law.
- B. Food prepared in a private home may not be used or offered for human consumption in a food establishment unless the home kitchen is inspected and approved by the Virginia Department of Agriculture and Consumer Services.
- C. Packaged food shall be labeled as specified in law, including 21 CFR 101 Food Labeling, 9 CFR 317 Labeling, Marking Devices, and Containers, and 9 CFR 381 Subpart N Labeling and Containers, and as specified under 12 VAC 5-421-400 and 410.
- D. Fish, other than molluscan shellfish, that are intended for consumption in their raw form and allowed as specified under 12 VAC 5-421-700 C 1 may be offered for sale or service if they are obtained from a supplier that freezes the fish as specified under 12 VAC 5-421-730; or frozen on the

premises as specified under 12 VAC 5-421-730 and records are retained as specified under 12 VAC 5-421-740.

- E. Whole-muscle, intact beef steaks that are intended for consumption in an undercooked form without a consumer advisory as specified in 12 VAC 5-421-700.C shall be:
 - 1. Obtained from a food processing plant that packages the steaks and labels them to indicate that they meet the definition of whole-muscle, intact beef; or
 - 2. If individually cut in a food establishment:
 - a. Cut from whole-muscle intact beef that is labeled by a food processing plant to indicate that the beef meets the definition of whole-muscle, intact beef,
 - b. Prepared so they remain intact, and
 - c. If packaged for undercooking in a food establishment, labeled to indicate that they meet the definition of whole-muscle, intact beef.
- F. Meat and poultry that is not a ready-to-eat food and is in a packaged form when it is offered for sale or otherwise offered for consumption, shall be labeled to include safe handling instructions as specified in law, including 9 CFR 317.2(l) and 9 CFR 381.125(b).

Condition 12 VAC 5-421-260 Sources 12 VAC 5-421-270

Refer to the public health reason for § 12 VAC 5-421-700.

Source

A primary line of defense in ensuring that food meets the requirements of § 12 VAC 5-421-260 is to obtain food from approved sources, the implications of which are discussed below. However, it is also critical to monitor food products to ensure that, after harvesting and processing, they do not fall victim to conditions that endanger their safety, make them adulterated, or compromise their honest presentation. The regulatory community, industry, and consumers should exercise vigilance in controlling the conditions to which foods are subjected and be alert to signs of abuse. FDA considers food in hermetically sealed containers that are swelled or leaking to be adulterated and actionable under the Federal Food, Drug, and Cosmetic Act. Depending on the circumstances, rusted and pitted or dented cans may also present a serious potential hazard.

Food, at all stages of production, is susceptible to contamination. The source of food is important because pathogenic microorganisms may be present in the breeding stock of farm

animals, in feeds, in the farm environment, in waters used for raising and freezing aquatic foods, and in soils and fertilizers in which plant crops are grown. Chemical contaminants that may be present in field soils, fertilizers, irrigation water, and fishing waters can be incorporated into food plants and animals.

Sources of molluscan shellfish are a particular concern because shellfish are frequently consumed raw or in an undercooked state and thus receive neither heat nor any other process that would destroy or inactivate microbial pathogens. For safety, these foods must be accompanied by certification that documents that they have been harvested from waters that meet the water quality standards contained in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. Certification also provides confidence that processing, packaging, and shipping have been conducted under sanitary conditions.

Food should be purchased from commercial supplies under regulatory control. Home kitchens, with their varieties of food and open entry to humans and pet animals, are frequently implicated in the microbial contamination of food. Because commercial items seldom are eaten right away, the home kitchen's limited capacity for maintaining food at proper temperatures may result in considerable microbial growth and toxin production by microorganisms introduced through the diverse sources of contamination. Controlled processing is required for the safe preparation of food entering commerce.

Labeling - General

Sources of packaged food must be labeled in accordance with law. Proper labeling of foods allows consumers to make informed decisions about what they eat. Many consumers, as a result of an existing medical condition, may be sensitive to specific foods or food ingredients. This sensitivity may result in dangerous medical consequences should certain foods or ingredients be unknowingly consumed. In addition, consumers have a basic right to be protected from misbranding and fraud.

On July 8, 1998, FDA announced in the Federal Register a final rule that revised its food labeling regulations to require a warning statement on fruit and vegetable juice products that have not been processed to prevent, reduce, or eliminate pathogenic microorganisms that may be present. FDA took this action to inform consumers, particularly those at greatest risk, of the hazard posed by such juice products. FDA expects that providing this information to consumers will allow them to make informed decisions on whether to purchase and consume such juice products, thereby reducing the incidence of foodborne illnesses and deaths caused by the consumption of these juices. At the time of publication of the 1999 Food Code, rulemaking had not been finalized regarding a mandatory Hazard Analysis Critical Control Point (HACCP) program for juice products.

Refer to Chapter 1 for the definition of juice. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which are commonly prepared for service to highly

susceptible populations. Untreated juices or beverages containing untreated juices that are offered to consumers as prepackaged foods must bear a warning statement as specified in 21 CFR Section 101.17(g). That statement is: "WARNING: This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems." Additional information is available in the document, "Guidance for Industry. Warning and Notice Statement: Labeling of Juice Products, Small Entity Compliance Guide" which can be found on the FDA Web Page http://www.cfsan.fda.gov/~dms/juicguid.html or obtained from the FDA Office of Food Labeling. Except for certain species of large tuna and raw molluscan shellfish, if fish are intended for raw consumption, they must be properly frozen before they are served. If this process is done offpremises, purchase specifications ensuring that proper freezing techniques are used to destroy parasites must be provided. This is necessary because fish from natural bodies of water may carry parasitic worms that can infect and injure consumers who eat such raw fish dishes as sushi, ceviche, green (lightly marinated) herring, and cold-smoked salmon. The worms are often deeply imbedded inside fish muscle. Thorough freezing kills these worms if the fish are subjected to a low enough temperature for a long enough time.

Labeling for Meat and Poultry

Retail food establishments that process and package meat or poultry in a form that is not ready-to-eat, are obligated by federal regulation to label the product with safe food handling instructions. The intent of this requirement is to ensure that all consumers are alerted to the fact that such products may contain bacteria and that food safety hinges upon their thoroughly cooking the product, regardless of where they obtain the products. That is, the labeling would exist if they obtain their meat and poultry at an establishment that handles only prepackaged and prelabeled products or if they obtain their meat or poultry at an operation such as a supermarket with a meat processing operation or from a small neighborhood butcher.

Labeling for Whole-muscle, Intact Beef Steaks

In order for a food establishment operator to know that a steak is a whole-muscle, intact cut of beef that can therefore be undercooked and served without a consumer advisory, the incoming product must be labeled. Processors can accommodate this need at the retail level by developing proposed labels, obtaining the necessary USDA Food Safety Inspection Service review and approval, and appropriately affixing the labels to their products.

12 VAC 5-421-280. Food in a Hermetically Sealed Container.*

3-201.12

Food in a hermetically sealed container shall be obtained from a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

Processing food at the proper high temperature for the appropriate time is essential to kill bacterial spores that, under certain conditions in an airtight container, begin to grow and produce toxin. Of special concern is the lethal toxin of **Clostridium botulinum**, an organism whose spores (i.e., survival stages for non-growth conditions) are found throughout the environment. Even slight underprocessing of low acid food which is canned can be dangerous, because spoilage microbes are killed and there are no signs to warn consumers that botulinum spores have germinated into vegetative cells and produced their toxin. If these foods are not processed to be commercially sterile, they must be received frozen or under proper refrigeration.

Refer also to the public health reason for §§ 12 VAC 5-421-260 and 12 VAC 5-421-270.

12 VAC 5-421-290. Fluid Milk and Milk Products. *

3-201.13

Fluid milk and milk products shall be obtained from sources that comply with Grade A standards as specified in law.

Milk, which is a staple for infants and very young children with incomplete immunity to infectious diseases, is susceptible to contamination with a variety of microbial pathogens such as **Escherichia coli** O157:H7, **Salmonella** spp., and **Listeria monocytogenes**, and provides a rich medium for their growth. This is also true of milk products. Pasteurization is required to eliminate pathogen contamination in milk and products derived from milk. Dairy products are normally perishable and must be received under proper refrigeration conditions.

12 VAC 5-421-300. Fish.*

3-201.14

- A. Fish that are received for sale or service shall be:
 - 1. Commercially and legally caught or harvested; or
 - 2. Approved for sale or service by a regulatory authority.
- B. Molluscan shellfish that are recreationally caught may not be received for sale or service.

After December 18, 1997, all processors of fish are required by 21 CFR 123 to have conducted a hazard analysis of their operation, identify each hazard that is reasonably likely to occur, and implement a HACCP plan to control each identified hazard. Retailers should assure that their seafood suppliers have complied with this requirement. Hazards known to be associated with specific fish species are discussed in the FDA Fish and Fishery Products Hazards and Controls Guide, available from the FDA Office of Seafood. Species-related hazards include pathogens, parasites, natural toxins, histamine, chemicals, and drugs.

The seafood implicated in histamine poisoning are the scombroid toxin-forming species, defined in 21 CFR 123.3(m) as meaning bluefish, mahi-mahi, tuna, and other species, whether or not in the family **Scrombridae**, in which significant levels of histamine may be produced in the fish flesh by decarboxylation of free histidine as a result of exposure of the fish after capture to temperatures that allow the growth of mesophilic bacteria.

Ciguatera toxin is carried to humans by contaminated fin fish from the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide. In the south Florida, Bahamian, and Caribbean regions, barracuda, amberjack, horse-eye jack, black jack, other large species of jack, king mackerel, large groupers, and snappers are particularly likely to contain ciguatoxin. Many other species of large predatory fishes may be suspect. In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect. Mackerel and barracuda are frequently ciguatoxic from mid to northeastern Australian waters.

12 VAC 5-421-310. Molluscan Shellfish.*

3-201.15

A. Molluscan shellfish shall be obtained from sources according to law and the requirements specified in the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, National Shellfish Sanitation Program Manual of Operations Part II Sanitation of the Harvesting, Processing and Distribution of Shellfish.

B. Molluscan shellfish received in interstate commerce shall be from sources that are listed in the Interstate Certified Shellfish Shippers List.

Pathogens found in waters from which molluscan shellfish are harvested can cause disease in consumers. Molluscan shellfish include: 1) oysters; 2) clams; 3) mussels; and, 4) scallops, except where the final product is the shucked adductor muscle only. The pathogens of concern include both bacteria and viruses.

Pathogens from the harvest area are of particular concern in molluscan shellfish because: 1) environments in which molluscan shellfish grow are commonly subject to contamination from sewage, which may contain pathogens, and to naturally occurring bacteria, which may also be pathogens; 2) molluscan shellfish filter and concentrate pathogens that may be present in surrounding waters; and, 3) molluscan shellfish are often consumed whole, either raw or partially cooked.

To minimize the risk of molluscan shellfish containing pathogens of sewage origin, State and foreign government agencies, called Shellfish Control Authorities, classify waters in which molluscan shellfish are found, based, in part, on an assessment of water quality. As a result of these classifications, molluscan shellfish harvesting is allowed from some waters, not from others, and only at certain times or under certain restrictions from others. Shellfish Control Authorities then exercise control over the molluscan shellfish harvesters to ensure that harvesting takes place only when and where it has been allowed.

Significant elements of Shellfish Control Authorities' efforts to control the harvesting of molluscan shellfish include: 1) a requirement that containers of in-shell molluscan shellfish (shellstock) bear a tag that identifies the type and quantity of shellfish, harvester, harvest location, and date of harvest; and, 2) a requirement that molluscan shellfish harvesters be licensed; 3) a requirement that processors that shuck molluscan shellfish or ship, reship, or repack the shucked product be certified; and, 4) a requirement that containers of shucked molluscan shellfish bear a label with the name, address, and certification number of the shucker-packer or repacker.

Pathogens, such as Vibrio vulnificus, Vibrio parahaemolyticus, Vibrio cholerae, and Listeria monocytogenes that may be present in low numbers at the time that molluscan shellfish are harvested, may increase to more hazardous levels if they are exposed to time/temperature abuse. To minimize the risk of pathogen growth, Shellfish Control Authorities place limits on the time between harvest and refrigeration. The length of time is dependant upon either the month of the year or the average monthly maximum air temperature (AMMAT) at the time of harvest, which is determined by the Shellfish Control Authority.

Paralytic shellfish poisoning (PSP) results from shellfish feeding upon toxic microorganisms such as dinoflagellates. In the U.S., PSP is generally associated with the consumption of mulluscan shellfish from the northeast and northwest coastal regions of the U.S. PSP in other parts of the world has been associated with molluscan shellfish from environments ranging from tropical to temperate waters. In addition, in the U.S., PSP toxin has recently been reported from the viscera of mackerel, lobster, dungeness crabs, tanner crabs, and red rock crabs.

Neurotoxic shellfish poisoning (NSP) in the U.S. is generally associated with the consumption of molluscan shellfish harvested along the coast of the Gulf of Mexico, and, sporadically, along the southern Atlantic coast. There has been a significant occurrence of toxins similar to NSP in New Zealand, and some suggestions of occurrence elsewhere.

For diarrhetic shellfish poisoning there has been no documented occurrence to date in the U.S. However, instances have been documented in Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, and eastern Canada.

Amnesic shellfish poisoning (ASP) is generally associated with the consumption of molluscan shellfish from the northeast and northwest coasts of North America. It has not yet been a problem in the Gulf of Mexico, although the algae that produce the toxin have been found there. ASP toxin has recently been identified as a problem in the viscera of dungeness crab, tanner crab, red rock crab, and anchovies along the west coast of the United States.

Marine toxins are not ordinarily a problem in scallops if only the adductor muscle is consumed. However, products such as roe-on scallops and whole scallops do present a potential hazard for natural toxins.

To reduce the risk of illness associated with raw shellfish consumption, the Food and Drug Administration (FDA) administers the National Shellfish Sanitation Program (NSSP). The NSSP

is a tripartite, cooperative action plan involving federal and state public health officials and the shellfish industry. Those groups work together to improve shellfish safety. States regularly monitor waters to ensure that they are safe before harvesting is permitted. FDA routinely audits the states' classification of shellfish harvesting areas to verify that none pose a threat to public health. Patrolling of closed shellfishing waters minimizes the threat of illegal harvesting or "bootlegging" from closed waters. Bootlegging is a criminal activity and a major factor in shellfish-borne illnesses. Purchases from certified dealers that adhere to NSSP controls is essential to keep risks to a minimum.

12 VAC 5-421-320. Wild mushrooms.*

3-201.16

A. Except as specified in Subsection B of this section, mushroom species picked in the wild shall be obtained from sources where each mushroom is individually inspected and found to be safe by an approved mushroom identification expert.

- B. This section does not apply to:
 - 1. Cultivated wild mushroom species that are grown, harvested, and processed in an operation that is regulated by the food regulatory agency that has jurisdiction over the operation; or
 - 2. Wild mushroom species if they are in packaged form and are the product of a food processing plant that is regulated by the food regulatory agency that has jurisdiction over the plant.

Over 5000 species of fleshy mushrooms grow naturally in North America. The vast majority have never been tested for toxicity. It is known that about 15 species are deadly and another 60 are toxic to humans whether they are consumed raw or cooked. An additional 36 species are suspected of being poisonous, whether raw or cooked. At least 40 other species are poisonous if eaten raw, but are safe after proper cooking.

Some wild mushrooms that are extremely poisonous may be difficult to distinguish from edible species. In most parts of the country there is at least one organization that include individuals who can provide assistance with both identification and program design. Governmental agencies, universities, and mycological societies are examples of such groups. If a food establishment chooses to sell wild mushrooms, management must recognize and address the need for a sound identification program for providing safe wild mushrooms.

Refer also to the public health reason for §§ 12 VAC 5-421-260 and 12 VAC 5-421-270.

- A. If game animals are received for sale or service they shall be:
 - 1. Commercially raised for food and:
 - a. Raised, slaughtered, and processed under a voluntary inspection program that is conducted by the agency that has animal health jurisdiction, or
 - b. Under a routine inspection program conducted by a regulatory agency other than the agency that has animal health jurisdiction, and
 - c. Raised, slaughtered, and processed according to:
 - (1) Laws governing meat and poultry as determined by the agency, and
 - (2) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee;
 - 2. Under a voluntary inspection program administered by the USDA for game animals such as exotic animals including animals (reindeer, elk, deer, antelope, water buffalo, or bison) that are "inspected and approved" in accordance with 9 CFR 352 Voluntary Exotic Animal Program or rabbits that are "inspected and certified" in accordance with 9CFR 354 Rabbit Inspection Program;
 - 3. As allowed by law, wild game animals that are live-caught are:
 - a. Under a routine inspection program conducted by a regulatory agency such as the agency that has animal health jurisdiction,
 - b. Slaughtered and processed according to:
 - (1) Laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and
 - (2) Requirements which are developed by the agency that has animal health jurisdiction and the agency that conducts the inspection program with consideration of factors such as the need for antemortem and postmortem examination by an approved veterinarian or veterinarian's designee; or

- 4. As allowed by law, for field-dressed wild game animals under a routine inspection program that ensures the animals:
 - a. Receive a postmortem examination by an approved veterinarian or veterinarian's designee, or
 - b. Are field-dressed and transported according to requirements specified by the agency that has animal health jurisdiction and the agency that conducts the inspection program, and
 - c. Are processed according to laws governing meat and poultry as determined by the agency that has animal health jurisdiction and the agency that conducts the inspection program.
- B. A game animal may not be received for sale or service if it is a species of wildlife that is listed in 50 CFR 17 Endangered and Threatened Wildlife and Plants.

The primary concern regarding game animals relates to animals obtained in the wild. Wild game animals may be available as a source of food only if a regulatory inspection program is in place to ensure that wild animal products are safe. This is important because wild animals may be carriers of viruses, rickettsiae, bacteria, or parasites that cause illness (zoonoses) in humans. Some of these diseases can be severe in the human host. In addition to the risk posed to consumers of game that is not subject to an inspection program, there is risk to those who harvest and prepare wild game because they may contract infectious diseases such as rabies or tularemia.

12 VAC 5-421-340. Temperature.*

3-202.11

- A. Except as specified in Subsection b of this section, refrigerated, potentially hazardous food shall be at a temperature of 41°F (5°C) or below when received.
- B. If a temperature other than 41°F (5°C) for a potentially hazardous food is specified in law governing its distribution, such as laws governing milk, molluscan shellfish, and shell eggs the food may be received at the specified temperature.
- C. Potentially hazardous food that is cooked to a temperature and for a time specified under 12 VAC 5-421-700 through 720 and received hot shall be at a temperature of 140°F (60°C) or above.
- D. A food that is labeled frozen and shipped frozen by a food processing plant shall be received frozen.

E. Upon receipt, potentially hazardous food shall be free of evidence of previous temperature abuse.

Temperature is one of the prime factors that controls the growth of bacteria in food. Many, though not all, types of pathogens and spoilage bacteria are prevented from multiplying to microbiologically significant levels in properly refrigerated foods that are not out of date. Effective August 27, 1999, federal regulations 7 CFR Part 59, Refrigeration and Labeling Requirements for Shell Eggs, (currently printed in the Federal Register, 63(166): 45663-45675) require shell eggs to be stored and transported in an ambient air temperature of no greater than 7°C (45°F).

High temperatures for a long enough time, such as those associated with thorough cooking, kill or inactivate many types of microorganisms. However, cooking does not always destroy the toxins produced in foods by certain bacteria (such as the enterotoxins of **Staphylococcus** aureus). Cooking or hot holding that follows temperature abuse may not make the food safe. Keeping cooked foods hot as required in the Code prevents significant regrowth of heat-injured microorganisms and prevents recontamination with bacteria that are newly introduced.

12 VAC 5-421-350. Additives.*

3-202.12

Food may not contain unapproved food additives or additives that exceed amounts allowed in 21 CFR, 170-180 relating to food additives, generally recognized as safe or prior sanctioned substances that exceed amounts allowed in 21 CFR, 181-186, substances that exceed amounts specified in 9 CFR 318.7 Approval of Substances for Use in the Preparation of Products, or pesticide residues that exceed provisions specified in 40 CFR 185 Tolerances for Pesticides in Food.

It is imperative for safety that food supplies come from sources that are in compliance with laws regarding chemical additives and contaminants.

Food additives are substances which, by their intended use, become components of food, either directly or indirectly. They must be strictly regulated. In excessive amounts or as a result of unapproved application, additives may be harmful to the consumer. Unintentional contaminants or residues also find their way into the food supply. The tolerances or safe limits designated for these chemicals are determined by risk assessment evaluations based on toxicity studies and consumption estimates.

12 VAC 5-421-360. Shell Eggs.*

3-202.13

Shell eggs shall be received clean and sound and may not exceed the restricted egg tolerances for U.S. Consumer Grade B as specified in 7 CFR Part 56 - Regulations Governing the Grading of Shell Eggs and U.S. Standards, Grades, and Weight classes for Shell Eggs, and 7 CFR Part 59 - Regulations Governing the Inspection of Eggs and Egg Products.

Damaged shells permit the entry of surface bacteria to the inside of eggs. Eggs are an especially good growth medium for many types of bacteria. Damaged eggs must not be used as food.

12 VAC 5-421-370. Eggs and Milk Products, Pasteurized.*

3-202.14

- A. Liquid, frozen, and dry eggs and egg products shall be obtained pasteurized.
- B. Fluid and dry milk and milk products complying with Grade A standards as specified in law shall be obtained pasteurized.
- C. Frozen milk products, such as ice cream, shall be obtained pasteurized in accordance with 21 CFR 135 Frozen Desserts.
- D. Cheese shall be obtained pasteurized unless alternative procedures to pasteurization are provided for in the CFR, such as 21 CFR 133 Cheeses and Related Cheese Products, for curing certain cheese varieties.

Liquid egg, fluid milk, and milk products are especially good growth media for many types of bacteria and must be pasteurized. Pasteurization is a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in these potentially hazardous foods. Freezing and drying of unpasteurized products will stop microbial growth and may reduce their bacterial populations; however, some organisms will survive because neither process invariably kills bacteria. Under certain conditions, freezing and drying may preserve microbes. An alternative to pasteurization may be applicable to certain cheese varieties cured or aged for a specified amount of time prior to marketing for consumption.

12 VAC 5-421-380. Package Integrity.*

3-202.15

Food packages shall be in good condition and protect the integrity of the contents so that the food is not exposed to adulteration or potential contaminants.

Damaged or incorrectly applied packaging may allow the entry of bacteria or other contaminants into the contained food. If the integrity of the packaging has been compromised, contaminants such as **Clostridium botulinum** may find their way into the food. In anaerobic conditions (lack of oxygen), botulism toxin may be formed.

Packaging defects may not be readily apparent. This is particularly the case with low acid canned foods. Close inspection of cans for imperfections or damage may reveal punctures or seam defects. In many cases, suspect packaging may have to be inspected by trained persons using magnifying equipment. Irreversible and even reversible swelling of cans (hard swells and flippers) may indicate can damage or imperfections (lack of an airtight, i.e., hermetic seal).

Swollen cans may also indicate that not enough heat was applied during processing (underprocessing). Suspect cans must be returned and not offered for sale.

12 VAC 5-421-390. Ice.*

3-202.16

Ice for use as a food or a cooling medium shall be made from drinking water.

Freezing does not invariably kill microorganisms; on the contrary, it may preserve them. Therefore, ice that comes into contact with food to cool it or that is used directly for consumption must be as safe as drinking water that is periodically tested and approved for consumption.

12VAC5-420-400. Shucked Shellfish, Packaging and Identification.

3-202.17

A. Raw shucked shellfish shall be obtained in nonreturnable packages which bear a legible label that identifies the:

- 1. Name, address, and certification number of the shucker-packer or repacker of the molluscan shellfish; and
- 2. The "sell by" date for packages with a capacity of less than one-half gallon (1,87 L) or the date shucked for packages with a capacity of one-half gallon (1.87 L) or more.
- B. A package of raw shucked shellfish that does not bear a label or which bears a label which does not contain all the information as specified under Subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

Plastic containers commonly used throughout the shellfish industry for shucked product bear specific information regarding the source of the shellfish as required by the NSSP Guide for the Control of Molluscan Shellfish. These containers must be nonreturnable so that there is no potential for their subsequent reuse by shellfish packers which could result in shucked product that is inaccurately identified by the label. The reuse of these containers within the food establishment must be assessed on the basis of the Food Code's criteria for multi-use containers and the likelihood that they will be properly relabeled to reflect their new contents.

12 VAC 5-421-410. Shellstock Identification.*

3-202.18

A. Shellstock shall be obtained in containers bearing legible source identification tags or labels that are affixed by the harvester and each dealer that depurates, ships, or reships the shellstock, as

specified in the National Shellfish Sanitation Program Manual of Operations, Part II Sanitation of the Harvesting, Processing and Distribution of Shellfish, and that list:

- 1. Except as specified under Subsection c of this section, on the harvester's tag or label, the following information in the following order:
 - a. The harvester's identification number that is assigned by the shellfish control authority,
 - b. The date of harvesting,
 - c. The most precise identification of the harvest location or aquaculture site that is practicable based on the system of harvest area designations that is in use by the shellfish control authority and including the abbreviation of the name of the state or country in which the shellfish are harvested,
 - d. The type and quantity of shellfish, and
 - e. The following statement in bold, capitalized type: "This tag is required to be attached until container is empty or retagged and thereafter kept on file for 90 days;" and
- 2. Except as specified under Subsection D of this section, on each dealer's tag or label, the following information in the following order:
 - a. The dealer's name and address, and the certification number assigned by the shellfish control authority,
 - b. The original shipper's certification number including the abbreviation of the name of the state or country in which the shellfish are harvested,
 - c. The same information as specified for a harvester's tag under subsections A 1 b through d of this section, and
 - d. The following statement in bold, capitalized type: "this tag is required to be attached until container is empty and thereafter kept on file for 90 days."
- B. A container of shellstock that does not bear a tag or label or that bears a tag or label that does not contain all the information as specified under Subsection A of this section shall be subject to a hold order, as allowed by law, or seizure and destruction in accordance with 21 CFR Subpart D Specific Administrative Decisions Regarding Interstate Shipments, Section 1240.60(d).

- C. If a place is provided on the harvester's tag or label for a dealer's name, address, and certification number, the dealer's information shall be listed first.
- D. If the harvester's tag or label is designed to accommodate each dealer's identification as specified under Subsections A 2 a and b of this section, individual dealer tags or labels need not be provided.

Accurate source identification of the harvesting area, harvester, and dealers must be contained on molluscan shellstock identification tags so that if a shellfish-borne disease outbreak occurs, the information is available to expedite the epidemiological investigation and regulatory action.

12 VAC 5-421-420. Shellstock, Condition.

3-202.19

When received by a food establishment, shellstock shall be reasonably free of mud, dead shellfish, and shellfish with broken shells. Dead shellfish or shellstock with badly broken shells shall be discarded.

Dirty, damaged, or dead shellstock can contaminate and degrade live and healthy shellstock and lead to foodborne illness. Harvesters have the primary responsibility for culling shellstock, but this responsibility continues throughout the distribution chain.

12 VAC 5-421-430. Molluscan Shellfish, Original Container.

3-203.11

- A. Except as specified in Subsection B and C of this section, molluscan shellfish may not be removed from the container in which they were received other than immediately before sale or preparation for service.
- B. Shellstock may be removed from the container in which they were received, displayed on drained ice, or held in a display container, and a quantity specified by a consumer may be removed from the display or display container and provided to the consumer if:
 - 1. The source of the shellstock on display is identified as specified under 12 VAC 5-421-410 and recorded as specified under 12 VAC 5-421-440; and
 - 2. The shellstock are protected from contamination.
- C. Shucked shellfish may be removed from the container in which they were received and held in a display container from which individual servings are dispensed upon a consumer's request if:

- 1. The labeling information for the shellfish on display as specified under 12 VAC 5-421-400 is retained and correlated to the date when, or dates during which, the shellfish are sold or served; and
- 2. The shellfish are protected from contamination.

Lot separation is critical to isolating shellfish implicated in illness outbreaks and tracking them to their source. Proper identification is needed for tracing the origin and determining conditions of shellfish processing and shipment. If the lots are commingled at retail, traceability is undermined and the root of the problem may remain undetected. If no causative factors are identified in the food establishment, tracing the incriminated lot helps in identifying products that need to be recalled or growing waters that may need to be closed to harvesting.

12 VAC 5-421-440. Shellstock, Maintaining Identification. *

3-203.12

- A. Except as specified under subsection B 2 of this section, shellstock tags shall remain attached to the container in which the shellstock are received until the container is empty.
- B. The identity of the source of shellstock that are sold or served shall be maintained by retaining shellstock tags or labels for 90 calendar days from the date the container is emptied by:
 - 1. Using an approved record keeping system that keeps the tags or labels in chronological order correlated to the date when, or dates during which, the shellstock are sold or served; and
 - 2. If shellstock are removed from their tagged or labeled container:
 - a. Using only 1 tagged or labeled container at a time, or
 - b. Using more than 1 tagged or labeled container at a time and obtaining a variance from the regulatory authority as specified in 12 VAC 5-421-3570 based on a HACCP plan that:
 - (1) Is submitted by the permit holder and approved by the regulatory authority as specified under 12 VAC 5-421-3580,
 - (2) Preserves source identification by using a record keeping system as specified under Subsection B of this section, and

(3) Ensures that shellstock from one tagged or labeled container are not commingled with shellstock from another container before being ordered by the consumer.

Accurate records that are maintained in a manner that allows them to be readily matched to each lot of shellstock provide the principal mechanism for tracing shellstock to its original source. If an outbreak occurs, regulatory authorities must move quickly to close affected growing areas or take other appropriate actions to prevent further illnesses. Records must be kept for 90 days to allow time for hepatitis A virus infections, which have an incubation period that is significantly longer than other shellfish-borne diseases, to come to light. The 90 day requirement is based on the following considerations:

Shelf-life of the product	14	days
Incubation period	56	days
Medical diagnosis and confirmation		
Reporting	5	days
Epidemiological investigation		
Total	90	days

Part III

Food

Article 3

Protection from Contamination after Receiving

12 VAC 5-421-450. Preventing Contamination from Hands.*

3-301.11

- A. Food employees shall wash their hands as specified under 12 VAC 5-421-140.
- B. Except when washing fruits and vegetables as specified under 12 VAC 5-421-510 or when otherwise approved, food employees should not contact exposed, ready-to-eat food with their bare hands and should use suitable utensils such as deli tissue, spatulas, tongs, single-use gloves or dispensing equipment.

C. Food employees shall minimize bare hand and arm contact with exposed food that is not in a ready-to-eat form. S

Refer to the public health reasons for §§ 12 VAC 5-421-130, 12 VAC 5-421-140, and 12 VAC 5-421-150.

Even though bare hands should never contact exposed, ready-to-eat food, thorough handwashing is important in keeping gloves or other utensils from becoming vehicles for transferring microbes to the food.

Clarification of ¶ 12 VAC 5-421-450(B) of the FDA Food Code with Respect to the Phrase "Except...when otherwise APPROVED"...

Background:

Infected food employees are the source of contamination in approximately one in five foodborne disease outbreaks reported in the United States with a bacterial or viral cause. Most of these outbreaks involve enteric, i.e., fecal-oral agents. These are organisms that employees were shedding in their stools at the time the food was prepared. Because of poor or nonexistent handwashing procedures, workers spread these organisms to the food. In addition, infected cuts, burns, or boils on hands can also result in contamination of food. Viral, bacterial, and parasitic agents can be involved.

Traditionally, food regulations have required two methods of preventing the spread of foodborne disease by this mode of transfer, i.e., they have prohibited food workers from preparing food when they are infectious and have required thorough and frequent handwashing. In order to strengthen fecal-oral transmission interventions, the Food Code provides focused and specific guidance about ill workers and when handwashing must occur. As a final barrier, bare-hand contact with ready-to-eat food (i.e., food that is edible without washing or is not subsequently subjected to a pathogen kill step) is prohibited and suitable utensils such as spatulas, tongs, single-use gloves, or dispensing equipment are required to be used. Any alternative to this requirement must convincingly address how food employees will be managed to preclude food contamination and how management will ensure that thorough handwashing occurs after employees use the toilet.

Objective:

The objective of this guidance is to provide clarification to \P 12 VAC 5-421-450(B) of the Food Code regarding the statement "except when otherwise approved." This guidance is provided to assist the regulatory authority in evaluating conformity with the principle of no bare-hand

contact through alternative practices and procedures. In this guidance, "hazard" means infected food workers spreading pathogens to food via the hands.

Guidance:

- I. Requirements prerequisite to consideration of alternatives include compliance with all Food Code provisions, particularly those related to:
 - (A) **Demonstration of Knowledge** specifically ¶¶ 12 VAC 5-421-60(A), (B), (C), and (H);
 - (B) Duties of the Person in Charge specifically ¶ 12 VAC 5-421-70(D);
 - (C) Employee Health regarding:
 - (1) Reporting of diseases and medical conditions, and
 - (2) Exclusions and restrictions, i.e., that food employees (including applicants to whom a conditional offer of employment has been made) report their health status as specified in Section 12 VAC 5-421-80; ill food employees are restricted or excluded as specified in Section 12 VAC 5-421-90; and the exclusions and restrictions are removed as specified in Section 12 VAC 5-421-100;
 - (D) **Personal Cleanliness, i.e., handwashing** procedures, including frequency and methodology of handwashing that ensure food employees keep their hands and fingertips clean and handwashing occurs at the times specified in Section 12 VAC 5-421-160 including after using the toilet and between tasks that may recontaminate the hands; and
 - (E) **Hygienic Practices** as specified in Part 2-4.
- II. FDA recommends that the acceptability of an alternative to no bare-hand contact should be based on evidence that at least the following are addressed:
 - (A) Why the operator of the food establishment is unable to comply with the Code requirement in \P 12 VAC 5-421-450(B);

¹Based on CDC Summary Surveillance for Foodborne-Disease Outbreaks - United States, 1988-1992 and New York State Department of Health data 1980-1991 published: Weingold, Guzewich, Fudala, 1994, Use of Foodborne Disease Data for HACCP Risk Assessment. J. Food Prot. 53: 820-830.

- (B) How the alternative practices and procedures will control the hazard through an active managerial control program. Such a program includes monitoring and verifying the institution of the prerequisite requirements described in Part I above and satisfies the following:
 - (1) **The public health hazard** associated with bare-hand contact specific to the food establishment operation **is identified and understood**. The regulatory authority needs assurance that the permit holder recognizes that the hazard being addressed is the possible contamination of ready-to-eat food by viral and parasitic as well as bacterial pathogens that are transferred from employees' hands.
 - (2) The ready-to-eat foods that will be contacted with bare hands are identified and both procedures and practices are in place so that food employees wash their hands before returning to their work station and cross-contamination from touching raw and ready-to-eat food is precluded.

For example, identifying the specific type of food to be prepared, such as tacos, and the specific location, such as a situation where a food employee is assigned solely to the designated taco work station. The work station is located immediately adjacent to the taco assembly unit and the employee will be preparing only the specified ready-to-eat food using bare hands.

Another example could be a food employee who is responsible solely for assembling a variety of ready-to-eat foods.

- (3) Institution of an effective training program for food employees which emphasizes not working when ill with any of the symptoms of foodborne illness, and explains good hygienic practices, proper handwashing procedures, and safe food preparation procedures. This should include a documented training plan that specifies how management responsibility for training has been designated, training program content, and the frequency of administration including periodic refresher sessions.
- (C) The alternative should clearly include monitoring, documentation, and verification to ensure that the practices and procedures are followed. Corrective actions need to be predetermined for situations where the practices and procedures are not followed, e.g., an ill employee is found preparing foods.
- III. Documentation of the practices, procedures, and corrective actions related to an alternative to no bare-hand contact with ready-to-eat food needs to be maintained and readily available at the food establishment at all times for use by the person-in-charge and for review by the regulatory authority.

- IV. The regulatory authority should also consider industry's elective use, managerial control, and monitoring and verification of additional preventive measures used in tandem with the aforementioned interventions which could include one or more of the following:
 - (A) Vaccination against hepatitis A for food employees including initial and booster shots or medical evidence that a food employee has had a previous illness from hepatitis A virus;
 - (B) Double handwashing;
 - (C) Use of nail brushes;
 - (D) Use of an FDA-accepted hand sanitizer after handwashing, i.e., approved as safe for application to human skin and safe as an indirect food additive, or exempted as a food additive under 21 CFR 170.39 Threshold of Regulation for Substances Used in Food Contact Articles; and
 - (E) Motivation for food employees not to work when they are ill.

12 VAC 5-421-460. Preventing Contamination When Tasting.*

3-301.12

A food employee may not use a utensil more than once to taste food that is to be sold or served.

12 VAC 5-421-470. Packaged and Unpackaged Food - Separation, Packaging, and Segregation.* **3-302.11**

- A. Food shall be protected from cross contamination by:
 - 1. Separating raw animal foods during storage, preparation, holding, and display from:
 - a. Raw ready-to-eat food including other raw animal food such as fish for sushi or molluscan shellfish, or other raw ready-to-eat food such as vegetables, and
 - b. Cooked ready-to-eat food;
 - 2. Except when combined as ingredients, separating types of raw animal foods from each other such as beef, fish, lamb, pork, and poultry during storage, preparation, holding, and display by:

- a. Using separate equipment for each type, or
- b. Arranging each type of food in equipment so that cross contamination of one type with another is prevented, and
- c. Preparing each type of food at different times or in separate areas;
- 3. Cleaning equipment and utensils as specified under 12 VAC 5-421-1780 A and sanitizing as specified under 12 VAC 5-421-1900;
- 4. Except as specified in Subsection B of this section, storing the food in packages, covered containers, or wrappings;
- 5. Cleaning hermetically sealed containers of food of visible soil before opening;
- 6. Protecting food containers that are received packaged together in a case or overwrap from cuts when the case or overwrap is opened;
- 7. Storing damaged, spoiled, or recalled food being held in the food establishment as specified under 12 VAC 5-421-3150; and
- 8. Separating fruits and vegetables, before they are washed as specified under 12 VAC 5-421-510 from ready-to-eat food.
- B. Subsection A 4 of this section does not apply to:
 - 1. Whole, uncut, raw fruits and vegetables and nuts in the shell, that require peeling or hulling before consumption;
 - 2. Primal cuts, quarters, or sides of raw meat or slab bacon that are hung on clean, sanitized hooks or placed on clean, sanitized racks;
 - 3. Whole, uncut, processed meats such as country hams, and smoked or cured sausages that are placed on clean, sanitized racks;
 - 4. Food being cooled as specified under 12 VAC 5-421-810 B 2; or,
 - 5. Shellstock.

Cross contamination can be avoided by separating raw animal foods from ready-to-eat foods. Cross contamination may also occur when raw unprepared vegetables contact ready-to-eat potentially hazardous foods. Raw animal foods must also be separated from each other because required cooking temperatures are based on thermal destruction data and anticipated microbial load. These parameters vary with different types of raw animal foods.

Food that is inadequately packaged or contained in damaged packaging could become contaminated by microbes, dust, or chemicals introduced by products or equipment stored in close proximity or by persons delivering, stocking, or opening packages or overwraps.

Packaging must be appropriate for preventing the entry of microbes and other contaminants such as chemicals. These contaminants may be present on the outside of containers and may contaminate food if the packaging is inadequate or damaged, or when the packaging is opened. The removal of food product overwraps may also damage the package integrity of foods under the overwraps if proper care is not taken.

12 VAC 5-421-480. Food Storage Containers, Identified with Common Name of Food. **3-302.12**

Working containers holding food or food ingredients that are removed from their original packages for use in the food establishment, such as cooking oils, flour, herbs, potato flakes, salt, spices, and sugar shall be identified with the common name of the food (in English and the common language of the food workers) except that containers holding food that can be readily and unmistakably recognized such as dry pasta need not be identified.

Certain foods may be difficult to identify after they are removed from their original packaging. Consumers may be allergic to certain foods or ingredients. The mistaken use of an ingredient, when the consumer has specifically requested that it not be used, may result in severe medical consequences.

The mistaken use of food from unlabeled containers could result in chemical poisoning. For example, foodborne illness and death have resulted from the use of unlabeled salt, instead of sugar, in infant formula and special dietary foods. Liquid foods, such as oils, and granular foods that may resemble cleaning compounds are also of particular concern.

12 VAC 5-421-490. Pasteurized Eggs, Substitute for Shell Eggs for Certain Recipes and Populations.* **3-302.13**

Pasteurized eggs or egg products shall be substituted for raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or bearnaise sauce, mayonnaise, and egg-fortified beverages that are not:

- 1. Cooked as specified in subsections 12 VAC 5-421-700 A 1 or 2 or
- 2. Included in subsection 12 VAC 5-421-700 D. The eggs are held before service following cooking.

Raw or undercooked eggs that are used in certain dressings or sauces are particularly hazardous because the virulent organism **Salmonella Enteritidis** may be present in raw shell eggs. Pasteurized eggs provide an egg product that is free of pathogens and is a ready-to-eat food. The pasteurized product should be substituted in a recipe that requires raw or undercooked eggs.

12 VAC 5-421-500. Protection from Unapproved Additives.*

3-302.14

- A. Food shall be protected from contamination that may result from the addition of, as specified in 12 VAC 5-421-350:
 - 1. Unsafe or unapproved food or color additives; and
 - 2. Unsafe or unapproved levels of approved food and color additives.
 - B. A food employee may not:
 - 1. Apply sulfiting agents to fresh fruits and vegetables intended for raw consumption or to a food considered to be a good source of vitamin B_1 ; or
 - 2. Serve or sell food specified in subsection B 1 of this section that is treated with sulfiting agents before receipt by the food establishment, except that grapes need not meet this subsection.

Refer to the public health reason for § 12 VAC 5-421-350.

Use of unapproved additives, or the use of approved additives in amounts exceeding those allowed by food additive regulations could result in foodborne illness, including allergic reactions. For example, many adverse reactions have occurred because of the indiscriminate use of sulfites to retard "browning" of fruits and vegetables or to cause ground meat to look "redder" or fresher.

The concern for misuse of additives also applies to food establishments operating under a variance and to Annex 6 Food Processing Criteria which addresses the use of sodium nitrite or other curing agents in smoking and curing operations. However, if this process is done incorrectly, it could cause illness or death because of excessive nitrite or because the food is insufficiently preserved.

12 VAC 5-421-510. Washing Fruits and Vegetables.

3-302.15

A. Raw fruits and vegetables shall be thoroughly washed in water to remove soil and other contaminants before being cut, combined with other ingredients, cooked, served, or offered for human consumption in ready-to-eat form except as specified in Subsection B of this section and except that whole, raw fruits and vegetables that are intended for washing by the consumer before consumption need not be washed before they are sold.

B. Fruits and vegetables may be washed by using chemicals as specified under 12 VAC 5-421-3390.

Pathogenic organisms and chemicals may be present on the exterior surfaces of raw fruits and vegetables. Washing removes the majority of organisms and/or chemicals present. If nondrinking water is used, the fruits and vegetables could become contaminated.

Toxic or undesirable residues could be present in or on the food if chemicals used for washing purposes are unapproved or applied in excessive concentrations.

On October 26, 1998 a voluntary guidance document which addresses practices commonly used by fresh fruit and vegetable producers was issued jointly by FDA, USDA, and CDC. This voluntary guidance contains useful information related to washing fruits and vegetables as well as the application of antimicrobial agents. The "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" is available from FDA's Food Safety Initiative staff and also on the Internet at http://www.fda.gov.

12 VAC 5-421-520. Ice Used as Exterior Coolant, Prohibited as Ingredient. **3-303.11**

After use as a medium for cooling the exterior surfaces of food such as melons or fish, packaged foods such as canned beverages, or cooling coils and tubes of equipment, ice may not be used as food.

Ice that has been in contact with unsanitized surfaces or raw animal foods may contain pathogens and other contaminants. For example, ice used to store or display fish or packaged foods could become contaminated with microbes present on the fish or packaging. If this ice is then used as a food ingredient, it could contaminate the final product.

12 VAC 5-421-530. Storage or Display of Food in Contact with Water or Ice. **3-303.12**

- A. Packaged food may not be stored in direct contact with ice or water if the food is subject to the entry of water because of the nature of its packaging, wrapping, or container or its positioning in the ice or water.
- B. Except as specified in Subsection C and D of this section, unpackaged food may not be stored in direct contact with undrained ice.
- C. Whole, raw fruits or vegetables; cut, raw vegetables such as celery or carrot sticks or cut potatoes; and tofu may be immersed in ice or water.
- D. Raw chicken and raw fish that are received immersed in ice in shipping containers may remain in that condition while in storage awaiting preparation, display, service, or sale.

Packages that are not watertight may allow entry of water that has been exposed to unsanitary exterior surfaces of packaging, causing the food to be contaminated. This may also result in the addition of water to the food that is unclaimed in the food's formulation and label.

Unpackaged foods such as fresh fish are often stored and/or displayed on ice. A potential for increasing the microbial load of a food exists because, as the ice melts, pathogens from one food may be carried by water to other foods. The potential for contamination is reduced by continuous draining of melting ice.

12 VAC 5-421-540. Food Contact with Equipment and Utensils.*

3-304.11

Food shall only contact surfaces of equipment and utensils that are cleaned as specified under 12 VAC 5-421-1770 through 1870 and sanitized as specified under 12 VAC 5-421-1880 through 1900.

Pathogens can be transferred to food from utensils that have been stored on surfaces which have not been cleaned and sanitized. They may also be passed on by consumers or employees directly, or indirectly from used tableware or food containers.

Some pathogenic microorganisms survive outside the body for considerable periods of time. Food that comes into contact directly or indirectly with surfaces that are not clean and sanitized is liable to such contamination. The handles of utensils, even if manipulated with gloved hands, are particularly susceptible to contamination.

Probe-type price or identification tags are defined as a utensil. This means that if such tags are for multiuse, they must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction. Probe-type price or product identification tags can cause microbial, chemical, or physical contamination if not properly designed, constructed, and maintained.

12 VAC 5-421-550. In-use Utensils, Between-use Storage.

3-304.12

During pauses in food preparation or dispensing, food preparation and dispensing utensils shall be stored:

- 1. Except as specified under Subsection 2 of this section, in the food with their handles above the top of the food and the container;
- 2. In food that is not potentially hazardous with their handles above the top of the food within containers or equipment that can be closed, such as bins of sugar, flour, or cinnamon;
- 3. On a clean portion of the food preparation table or cooking equipment only if the in-use utensil and the food-contact surface of the food preparation table or cooking equipment are cleaned and sanitized at a frequency specified under 12 VAC 5-421-1780 and 12 VAC 5-421-1890;
- 4. In running water of sufficient velocity to flush particulates to the drain, if used with moist food such as ice cream or mashed potatoes; or
- 5. In a clean, protected location if the utensils, such as ice scoops, are used only with a food that is not potentially hazardous.
- 6. In a container of water if the water is maintained at a temperature of at least 140°F (60°C) and the container is cleaned at a frequency specified under section 12 VAC 5-421-1780 D 7.

Refer to the public health reason for § 12 VAC 5-421-540.

Once a food employee begins to use a utensil such as a ladle, spatula, or knife, that has been previously cleaned and sanitized, it is then considered an in-use utensil. In-use utensils, used on a continuous or intermittent basis during preparation or dispensing, must be cleaned and sanitized on a schedule that precludes the growth of pathogens that may have been introduced onto utensil surfaces. In-use utensils may be safely stored in hot water maintained at 140°F or above during intermittent use because microbial growth is controlled at such temperatures.

12 VAC 5-421-560. Linens and Napkins, Use Limitation.

3-304.13

Linens and napkins may not be used in contact with food unless they are used to line a container for the service of foods and the linens and napkins are replaced each time the container is refilled for a new customer.

Refer to the public health reason for § 12 VAC 5-421-540.

Because of their absorbency, linens and napkins used as liners that contact food must be replaced whenever the container is refilled. Failure to replace such liners could cause the linens or napkins to become fomites.

12 VAC 5-421-570. Wiping Cloths, Use Limitation.

3-304.14

- A. Cloths that are in use for wiping food spills shall be used for no other purpose.
- B. Cloths used for wiping food spills shall be:
 - 1. Dry and used for wiping food spills from tableware and carry-out containers; or
 - 2. Wet and cleaned as specified under 12 VAC 5-421-1920 D, stored in a chemical sanitizer at a concentration specified in 12 VAC 5-421-3380, and used for wiping spills from food-contact and nonfood-contact surfaces of equipment.
- C. Dry or wet cloths that are used with raw animal foods shall be kept separate from cloths used for other purposes, and moist cloths used with raw animal foods shall be kept in a separate sanitizing solution.
- D. Wet wiping cloths used with a freshly made sanitizing solution and dry wiping cloths shall be free of food debris and visible soil.

Refer to the public health reason for § 12 VAC 5-421-540.

Soiled wiping cloths, especially when moist, can become breeding grounds for pathogens that could be transferred to food. Any wiping cloths that are not dry (except those used once and then laundered) must be stored in a sanitizer solution at all times, with the proper sanitizer concentration in the solution. Wiping cloths soiled with organic material can overcome the effectiveness of, and neutralize, the sanitizer. The sanitizing solution must be changed as needed to minimize the accumulation of organic material and sustain proper concentration. Proper sanitizer concentration should be ensured by checking the solution periodically with an appropriate chemical test kit.

12 VAC 5-421-580. Gloves, Use Limitation.

3-304.15

- A. If used, single-use gloves shall be used for only one task such as working with ready-to-eat food or with raw animal food, used for no other purpose, and discarded when damaged or soiled, or when interruptions occur in the operation.
- B. Except as specified in Subsection C of this section, slash-resistant gloves that are used to protect the hands during operations requiring cutting shall be used in direct contact only with food that is subsequently cooked as specified under 12 VAC 5-421-700 through 760 such as frozen food or a primal cut of meat.
- C. Slash-resistant gloves may be used with ready-to-eat food that will not be subsequently cooked if the slash-resistant gloves have a smooth, durable, and nonabsorbent outer surface; or if the slash-resistant gloves are covered with a smooth, durable, nonabsorbent glove, or a single-use glove.
- D. Cloth gloves may not be used in direct contact with food unless the food is subsequently cooked as required under 12 VAC 5-421-700 through 760 such as frozen food or a primal cut of meat.

Refer to the public health reason for §12 VAC 5-421-540.

Gloves used in handling ready-to-eat food are defined as a "utensil." This means that gloves used for food contact must meet the criteria listed in Parts 4-1 Materials for Construction and Repair, and 4-2 Design and Construction.

All gloves used in direct contact with food must meet FDA criteria for indirect food additives. The FDA, Office of Premarket Approval, Indirect Additives, reviews gloves submitted for food-contact use in the food industry on the basis of the glove's formulation or components.

Multiuse gloves, especially when used repeatedly and soiled, can become breeding grounds for pathogens that could be transferred to food. Soiled gloves can directly contaminate food if stored with ready-to-eat food or may indirectly contaminate food if stored with articles that will be used in contact with food.

Natural rubber latex gloves have been reported to cause allergic reactions in some individuals who wear latex gloves during food preparation, and even in individuals eating food prepared by food employees wearing latex gloves (refer to Annex 2 for this section). This information should be taken into consideration when deciding whether single-use gloves made of latex will be used during food preparation.

Slash-resistant gloves are not easily cleaned and sanitized. Their use with ready-to-eat foods could contaminate the food.

12 VAC 5-421-590. Using Clean Tableware for Second Portions and Refills. **3-304.16**

- A. Except for refilling a consumer's drinking cup or container without contact between the pouring utensil and the lip contact area of the drinking cup or container, food employees may not use tableware, including single-service articles, soiled by the consumer to provide second portions or refills.
- B. Except as specified in Subsection C of this section, self-service consumers may not be allowed to use soiled tableware, including single-service articles, to obtain additional food from the display and serving equipment.
- C. Cups and glasses may be reused by self-service consumers or food employees if refilling is a contamination-free process as specified under 12 VAC 5-421-1230 1, 2 and 4.

12 VAC 5-421 -600. Refilling Returnables.

3-304.17

- A. A take-home food container returned to a food establishment may not be refilled at a food establishment with a potentially hazardous food.
- B. Except as specified in Subsection C, a take-home food container refilled with food that is not potentially hazardous shall be cleaned as specified under 12 VAC 5-421-1870.
- C. Personal take-out beverage containers, such as thermally insulated bottles, non-spill coffee cups and promotional beverage glasses, may be refilled by employees or the consumer if refilling is a contamination-free process as specified under 12 VAC 5-421-1230 1, 2 and 4.

Refer to the public health reason for § 12 VAC 5-421-540.

12 VAC 5-421-610. Food Storage.

3-305.11

- A. Except as specified in Subsection B and C of this section, food shall be protected from contamination by storing the food:
 - 1. In a clean, dry location;
 - 2. Where it is not exposed to splash, dust, or other contamination; and
 - 3. At least 6 inches (15 cm) above the floor.
- B. Food in packages and working containers may be stored less than 6 inches (15 cm) above the floor on case lot handling equipment as specified under 12 VAC 5-421-1420.

C. Pressurized beverage containers, cased food in waterproof containers such as bottles or cans, and milk containers in plastic crates may be stored on a floor that is clean and not exposed to floor moisture.

12 VAC 5-421-620. Food Storage, Prohibited Areas.

3-305.12

Food may not be stored:

- 1. In locker rooms;
- 2. In toilet rooms or their vestibules;
- 3. In dressing rooms;
- 4. In garbage rooms;
- 5. In mechanical rooms;
- 6. Under sewer lines that are not shielded to intercept potential drips;
- 7. Under leaking water lines, including leaking automatic fire sprinkler heads, or under lines on which water has condensed;
- 8. Under open stairwells; or
- 9. Under other sources of contamination.

Preventing
Contamination
from the

Premises

12 VAC 5-421-610 12 VAC 5-421-620 Food Storage.

Food Storage, Prohibited Areas.

Pathogens can contaminate and/or grow in food that is not stored properly. Drips of condensate and drafts of unfiltered air can be sources of microbial contamination for stored food. Shoes carry contamination onto the floors of food preparation and storage areas. Even trace amounts of refuse or wastes in rooms used as toilets or for dressing, storing garbage or implements, or housing machinery can become sources of food contamination. Moist conditions in storage areas promote microbial growth.

12 VAC 5-421-630. Vended Potentially Hazardous Food, Original Container.

3-305.13

Potentially hazardous food dispensed through a vending machine shall be in the package in which it was placed at the food establishment or food processing plant at which it was prepared.

The possibility of product contamination increases whenever food is exposed. Changing the container(s) for machine vended potentially hazardous food allows microbes that may be present an opportunity to contaminate the food. Pathogens could be present on the hands of the individual packaging the food, the equipment used, or the exterior of the original packaging. In addition, many potentially hazardous foods are vended in a hermetically sealed state to ensure product safety. Once the original seal is broken, the food is vulnerable to contamination.

12 VAC 5-421-640. Food Preparation.

3-305.14

During preparation, unpackaged food shall be protected from environmental sources of contamination.

Food preparation activities may expose food to an environment that may lead to the food's contamination. Just as food must be protected during storage, it must also be protected during preparation. Sources of environmental contamination may include splash from cleaning operations, drips form overhead air conditioning vents, or air from an uncontrolled atmosphere such as may be encountered when preparing food in a building that is not constructed according to Food Code requirements.

12 VAC 5-421-650. Food Display.

3-306.11

Except for nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling, or washing by the consumer before consumption, food on display shall be protected from contamination by the use of packaging; counter, service line, or salad bar food guards; display cases; or other effective means.

During display, food can be contaminated even when there is no direct hand contact. Many microbes can be conveyed considerable distances on air currents through fine sprays or aerosols. These may originate from people breathing or sneezing, water sprays directed at drains, or condensate from air conditioners. Even wind gusts across sewage deposits and fertilized fields have been known to contaminate food in adjacent establishments where food was unprotected.

12 VAC 5-421-660. Condiments, Protection.

3-306.12

- A. Condiments shall be protected from contamination by being kept in dispensers that are designed to provide protection, protected food displays provided with the proper utensils, original containers designed for dispensing, or individual packages or portions.
- B. Condiments at a vending machine location shall be in individual packages or provided in dispensers that are filled at a location that is approved by the regulatory authority, such as the food establishment that provides food to the vending machine location, a food processing plant that is regulated by the agency that has jurisdiction over the operation, or a properly equipped facility that is located on the site of the vending machine location.

Unpackaged condiments are exposed to contamination by consumers who could be suffering from a disease transmissible through food. Once the condiments are contaminated, subsequent consumers using the condiments may be exposed to pathogens. Condiments in individual packages are protected from consumer contamination.

On- or off-site facilities for refilling condiment dispensers must be adequately equipped to ensure that the filling operation does not introduce contaminants.

12 VAC 5-421-670. Consumer Self-service Operations.*

3-306.13

- A. Raw, unpackaged animal food, such as beef, lamb, pork, poultry, and fish may not be offered for consumer self-service. This subsection does not apply to consumer self-service of ready-to-eat foods at buffets or salad bars that serve foods such as sushi or raw shellfish, or to ready-to-cook individual portions for immediate cooking and consumption on the premises such as consumer-cooked meats or consumer-selected ingredients for Mongolian barbecue.
- B. Consumer self-service operations for ready-to-eat foods shall be provided with suitable utensils or effective dispensing methods that protect the food from contamination. N
- C. Consumer self-service operations such as buffets and salad bars shall be monitored by food employees trained in safe operating procedures. ^N

Raw foods of animal origin usually contain pathogens. In addition, these foods, if offered for consumer self-service, could cross contaminate other foods stored in the same display. Because raw foods of animal origin are assumed to be contaminated and do provide an ideal medium for the growth of pathogenic organisms, they should not be available for consumer self-service. Self-service operations of ready-to-eat foods also provide an opportunity for contamination by consumers. The risk of contamination can be reduced by supplying clean

utensils and dispensers and by employee monitoring of these operations to ensure that the utensils and dispensers are properly used.

Bean sprouts that are displayed in produce areas for consumer self-service are potentially hazardous foods and appropriate refrigeration must be maintained. However, they are not considered ready-to-eat since they are intended to be washed by the consumer before consumption.

12 VAC 5-421-680. Returned Food and Reservice of Food.*

3-306.14

- A. Except as specified under Subsection B of this section, after being served or sold and in the possession of a consumer, food that is unused or returned by the consumer may not be offered as food for human consumption.
- B. Except as specified under 12 VAC 5-421-950 3, a container of food that is not potentially hazardous may be transferred from one consumer to another if:
 - 1. The food is dispensed so that it is protected from contamination and the container is closed between uses such as a narrow-neck bottle containing catsup, steak sauce, or wine; or
 - 2. The food, such as crackers, salt or pepper is in an unopened original package and maintained in sound condition.

Food can serve as a means of person-to-person transmission of disease agents such as hepatitis A virus. Any unpackaged foods, even bakery goods in a bread basket that are not potentially hazardous and that have been served to a consumer, but not eaten, can become vehicles for transmitting pathogenic microorganisms from the initial consumer to the next if the food is served again.

12 VAC 5-421-690. Miscellaneous Sources of Contamination.

3-307.11

Food shall be protected from contamination that may result from a factor or source not specified under 12 VAC 5-421-450 through 12 VAC 5-421-680.

This Code section provides a category in which to capture sources of contamination not specifically delineated in Subparts 3-301 through 306. Codes prior to 1993 had such a provision for addressing food contamination for reasons other than those elsewhere specified. Regardless of its specificity, a Code can not anticipate all the diverse means by which food can become contaminated after receipt.

Part III

Food

Article 4

Destruction of Organisms of Public Health Concern

12 VAC 5-421-700. Raw Animal Foods.*

3-401.11

- A. Except as specified under Subsection B and in Subsections C and D of this section, raw animal foods such as eggs, fish, meat, poultry, and foods containing these raw animal foods, shall be cooked to heat all parts of the food to a temperature and for a time that complies with one of the following methods based on the food that is being cooked:
 - 1. 145°F (63°C) or above for 15 seconds for:
 - a. Raw shell eggs that are broken and prepared in response to a consumer's order and for immediate service, and
 - b. Except as specified under subsections A 2 and 3 and Subsection B of this section, fish, meat, and pork including game animals commercially raised for food as specified under subsection 12 VAC 5-421-330 A 1 and game animals under a voluntary inspection program as specified under subsection 12 VAC 5-421-330 A 2;
 - 2. 155°F (68°C) for 15 seconds or the temperature specified in the following chart that corresponds to the holding time for ratites and injected meats; the following if they are comminuted: fish, meat, game animals commercially raised for food as specified under subsection 12 VAC 5-421-330 A 1, and game animals under a voluntary inspection program as specified under subsection 12 VAC 5-421-330 A 2; and raw eggs that are not prepared as specified under subsection A 1 a of this section:

Minimum			
Temperature	Time		
°F (°C)			
145 (63)	3 minutes		
150 (66)	1 minute		
158 (70)	<1 second (instantaneous)		

- 3. 165°F (74°C) or above for 15 seconds for poultry, wild game animals as specified under subsections 12 VAC 5-421-330 A 3, stuffed fish, stuffed meat, stuffed pasta, stuffed poultry, stuffed ratites, or stuffing containing fish, meat, or poultry.
- B. Whole beef roasts, corned beef roasts, pork roasts, and cured pork roasts such as ham shall be cooked:
 - 1. In an oven that is preheated to the temperature specified for the roast's weight in the following chart and that is held at that temperature:

Oven Type	Oven Temperature Based on Roast Weight	
	Less than 10 lbs (4.5 kg)	10 lbs (4.5 kg) or more
Still Dry	350°F (177°C) or more	250°F (121°C) or more
Convection	325°F (163°C) or more	250°F (121°C) or more
High humidity ¹	250°F (121°C) or less	250°F (121°C) or less

Relative humidity greater than 90% for at least 1 hour as measured in the cooking chamber or exit of the oven; or in a moisture-impermeable bag that provides 100% humidity.

; and

2. As specified in the following chart, to heat all parts of the food to a temperature and for the holding time that corresponds to that temperature:

Temperature	Time ¹				
°F (°C)	in minutes				
130 (54)	121	136 (58)	32	142 (61)	8
132 (56)	77	138 (59)	19	144 (62)	5
134 (57)	47	140 (60)	12	145 (63)	3
¹ Holding time may include postoven heat rise.					

- C. A raw or undercooked whole-muscle, intact beef steak may be served or offered for sale in a ready-to-eat form if:
 - 1. The food establishment serves a population that is not a highly susceptible population,
 - 2. The steak is labeled, as specified under 12 VAC 5-421-270 E, to indicate that it meets the definition of "whole-muscle, intact beef", and
 - 3. The steak is cooked on both the top and bottom to a surface temperature of 145°F (63°C) or above and a cooked color change is achieved on all external surfaces.
- D. A raw animal food such as raw egg, raw fish, raw-marinated fish, raw molluscan shellfish, or steak tartare; or a partially cooked food such as lightly cooked fish, soft cooked eggs, or rare meat other than whole-muscle, intact beef steaks as specified in Subsection C of this section, may be served or offered for sale in a ready-to-eat form if:
 - 1. The food establishment serves a population that is not a highly susceptible population, and
 - 2. The regulatory authority grants a variance from Subsection A or B of this section as specified in 12 VAC 5-421-3570 based on a HACCP plan that:
 - a. Is submitted by the permit holder and approved as specified under 12 VAC 5-421-3580,
 - b. Documents scientific data or other information showing that a lesser time and temperature regimen results in a safe food, and

c. Verifies that equipment and procedures for food preparation and training of food employees at the food establishment meet the conditions.

Cooking 12 VAC 5-421-700 Raw Animal Foods.*
12 VAC 5-421-710 Microwave Cooking.*
12 VAC 5-421-720 Plant Food Cooking for Hot Holding.

Cooking, to be effective in eliminating pathogens, must be adjusted to a number of factors. These include the anticipated level of pathogenic bacteria in the raw product, the initial temperature of the food, and the food's bulk which affects the time to achieve the needed internal product temperature. Other factors to be considered include post-cooking heat rise and the time the food must be held at a specified internal temperature.

Greater numbers and varieties of pathogens generally are found on poultry than on other raw animal foods. Therefore, a higher temperature, in combination with the appropriate time is needed to cook these products.

To kill microorganisms, food must be held at a sufficient temperature for the specified time. Cooking is a scheduled process in which each of a series of continuous time/temperature combinations can be equally effective. For example, in cooking a beef roast, the microbial lethality achieved at 121 minutes after it has reached 54°C (130°F) is the same lethality attained as if it were cooked for 3 minutes after it has reached 63°C (145°F).

Cooking requirements are based in part on the biology of pathogens. The thermal destruction of a microorganism is determined by its ability to survive heat. Different species of microorganisms have different susceptibilities to heat. Also, the growing stage of a species (such as the vegetative cell of bacteria, the trophozoite of protozoa, or the larval form of worms) is less resistant than the same organism's survival form (the bacterial spore, protozoan cyst, or worm egg).

Food characteristics also affect the lethality of cooking temperatures. Heat penetrates into different foods at different rates. High fat content in food reduces the effective lethality of heat. High humidity within the cooking vessel and the moisture content of food aid thermal destruction.

Heating a large roast too quickly with a high oven temperature may char or dry the outside, creating a layer of insulation that shields the inside from efficient heat penetration. To kill all pathogens in food, cooking must bring all parts of the food up to the required temperatures for the correct length of time.

The temperature and time combination criteria specified in Part 3-4 of this Code are based on the destruction of Salmonellae. This Part includes temperature and time parameters that provide "D" values (decimal log reduction values) that may surpass 7D. For example, at 63°C(145°F), a time span of 15 seconds will provide a 3D reduction of Salmonella Enteritidis in eggs. This organism, if present in raw shell eggs, is generally found in relatively low numbers. Other foods,

uncomminuted fish and meats including commercially raised game animal meat, specified as acceptable for cooking at this temperature and time parameter are expected to have a low level of internal contamination. The parameters are expected to provide destruction of the surface contaminants on these foods.

Seared Steak

The provision for allowing seared steaks was reviewed by the National Advisory Committee for Microbiological Criteria for Foods (NACMCF) and USDA. Paragraph 12 VAC 5-421-700(C) includes their recommendations.

USDA comments included, "For the purposes of this discussion, steak is a whole beef muscle. It does not include whole beef muscle that has been pinned, injected, or chopped and formed. It may be cut cross grain, such as sirloin, chuck, or porterhouse; or it may be cut with the grain, such as flank, skirt, or Chateaubriand. Other species, such as poultry, pork and lamb, are not included."

NACMCF comments included, "Due to the low probability of pathogenic organisms being present in or migrating from the external surface to the interior of beef muscle, cuts of intact muscle (steaks) should be safe if the external surfaces are exposed to temperatures sufficient to effect a cooked color change. In addition, the cut (exposed) surfaces must receive additional heat to effect a complete sear across the cut surfaces. Grill or char marks may be applied to the complete surface searing. The meat should be seared on both top and bottom surfaces utilizing a heating environment (e.g., grill or broiling oven) that imparts a temperature at the surface of the intact steak of at least 145°F to achieve a cooked color change on all external surfaces. The searing of all surfaces should be continuous until the desired degree of doneness and appearance are attained. This is considered a ready to eat food."

As reflected in the definition of "whole-muscle, intact beef steak," marination is a food safety concern when the fascia (exterior surface) of the steak is broken by scoring or other means which allows the marinade to penetrate, and potentially contaminate, the interior of the steak. In such cases, the Code allowance for undercooking without a consumer advisory is negated.

Pork

In pork, **Trichinella spiralis**, **Toxoplasma gondii**, and **Taenia solium**, parasites causing foodborne illness, are inactivated at temperatures below 145°F. Therefore, pork roasts can be cooked like beef roasts (e.g., 145°F for 3 minutes) and pork chops cooked like steaks to achieve an internal temperature of 145°F for 15 seconds. Based on the Goodfellow and Brown study, a 5D reduction of organisms is achieved at 68°C (155°F) for 15 seconds for the following foods: ratites and injected meats and comminuted: fish, meat, game animals commercially raised for food, and game animals that come under a USDA voluntary inspection program. Ratites such as ostrich, emu, and rhea are included in this list of raw animals foods because when cooked to a temperature greater than 68°C (155°F), ratites exhibit a (metallic) "off" taste.

When USDA established the time and temperature parameters for 9 CFR 318.23 (known as the "patty rule"), the Agency based the 5D for Salmonella on extrapolations applied to the research done by Goodfellow and Brown to account for the lack of a "come up, come down" time in the thin, small mass beef patties. Consequently, there is no linear relationship between the patty rule and roast beef time and temperature parameters. The patty rule also provided for an 8D reduction in the number of **E. coli**. The time and temperature requirements in the Food Code for comminuted meats are comparable to the USDA requirements.

Temperature for Comminuted Meat at Less Than 1 Second

In the "Report of the Task Force on Technical Issues Arising from the National Advisory Committee for Microbiological Criteria for Foods' (NACMCF) Review of the Meat Patty Proposal" (undated), it is stated on page 7, in Option (A), that:

"Based on the 1998 research data ... and an assumption that instantaneous is defined as eight seconds, manufacturers would be required to process fully-cooked meat patties at a temperature of 157°F. Given the lack of any significant margin of safety in this process, there should be no deviation below the 158°F requirement."

In November, 1997, the NACMCF Meat and Poultry Subcommittee revisited the time and temperatures for cooking hamburger and advised FDA that cooking hamburger to 158°F for less than one second is an adequate cook based on the following:

- 1. The cooking recommendations contained in the Food Code and in USDA guidance provide a large margin of safety for killing vegetable enteric pathogens;
- 2. The concept of integrated lethality (the kill imparted during the entire heating and cooling process) adds to the margin of safety; and
- 3. The time component of the time and temperature requirement will be exceeded before the temperature can be determined.

The parameters for cooking poultry, wild game animal meats, stuffed food products, etc., of $74^{\circ}C(165^{\circ}F)$ or above for 15 seconds yield greater than a 7D reduction.

12 VAC 5-421-710. Microwave Cooking.*

3-401.12

Raw animal foods cooked in a microwave oven shall be:

- 1. Rotated or stirred throughout or midway during cooking to compensate for uneven distribution of heat;
- 2. Covered to retain surface moisture;

- 3. Heated to a temperature of at least 165°F (74°C) in all parts of the food; and
- 4. Allowed to stand covered for 2 minutes after cooking to obtain temperature equilibrium.

The rapid increase in food temperature resulting from microwave heating does not provide the same cumulative time and temperature relationship necessary for the destruction of microorganisms as do conventional cooking methods. In order to achieve comparable lethality, the food must attain a temperature of 74°C (165°F) in all parts of the food. Since cold spots may exist in food cooking in a microwave oven, it is critical to measure the food temperature at multiple sites when the food is removed from the oven and then allow the food to stand covered for two minutes post microwave heating to allow thermal equalization and exposure. Although some microwave ovens are designed and engineered to deliver energy more evenly to the food than others, the important factor is to measure and ensure that the final temperature reaches 74°C (165°F) throughout the food.

"The factors that influence microwave thermal processes include many of the same factors that are important in conventional processes (mass of objects, shape of objects, specific heat and thermal conductivity, etc.). However, other factors are unique in affecting microwave heating, due to the nature of the electric field involved in causing molecular friction. These factors are exemplified by moisture and salt contents of foods, which play a far more important role in microwave than conventional heating." (Reference: Heddelson and Doores, see Annex 2)

12 VAC 5-421-720. Plant Food Cooking for Hot Holding.

3-401.13

Fruits and vegetables that are cooked for hot holding shall be cooked to a temperature of $140^{\circ}F$ ($60^{\circ}C$).

Fruits and vegetables that are fresh, frozen, or canned and that are heated for hot holding need only to be cooked to the temperature required for hot holding. These foods do not require the same level of microorganism destruction as do raw animal foods since these fruits and vegetables are ready-to-eat at any temperature. Cooking to the hot holding temperature of 60° C (140° F) prevents the growth of pathogenic bacteria that may be present in or on these foods. In fact, the level of bacteria will be reduced over time at the specified hot holding temperature.

12 VAC 5-421-730. Parasite Destruction.*

3-402.11

A. Except as specified in Subsection B of this section, before service or sale in ready-to-eat form, raw, marinated, partially cooked or marinated-partially cooked fish other than molluscan shellfish shall be frozen throughout to a temperature of:

- 1. -4°F (-20°C) or below for 168 hours (7 days) in a freezer; or
- 2. -35°c (-31°f) or below for 15 hours in a blast freezer.
- B. If the fish are tuna of the species Thunnus alalunga, Thunnus albacares (Yellowfin tuna), Thunnus atlanticus, Thunnus maccoyii (Bluefin tuna, Southern), Thunnus obesus (Bigeye tuna), or Thunnus thynnus (Bluefin tuna, Northern), the fish may be served or sold in a raw, raw-marinated, or partially cooked ready-to-eat form without freezing as specified under Subsection A of the section.

Refer to the public health reason for § 12 VAC 5-421-270.

Lightly cooked, raw, raw-marinated, and cold-smoked fish may be desired by consumers for taste or perceived nutritional reasons. In order to ensure destruction of parasites, fish may be frozen before service as an alternative public health control to that which is provided by adequate cooking. Candling or other visual inspection techniques are not adequate to avoid the risk of parasites from fish which have not been frozen.

In response to information provided to the FDA Office of Seafood, the Fish and Fishery Hazards and Controls Guide lists certain species of tuna as not being susceptible to parasites of concern and therefore are exempted from the freezing requirements for other fish species that are consumed raw.

12 VAC 5-421-740. Records, Creation and Retention.

3-402.12

- A. Except as specified in 12 VAC 5-421-730 B and Subsection B of this section, if raw, marinated, raw-marinated, partially cooked, or marinated-partially cooked fish are served or sold in ready-to-eat form, the person in charge shall record the freezing temperature and time to which the fish are subjected and shall retain the records at the food establishment for 90 calendar days beyond the time of service or sale of the fish.
- B. If by a supplier, a written agreement or statement from the supplier stipulating that the fish supplied are frozen to a temperature and for a time specified under 12 VAC 5-421-730 may substitute for the records specified under Subsection A of this section.

Records must be maintained to verify that the critical limits required for food safety are being met. Records the fish are frozen provide a check for both the operator and the regulator in determining that monitoring and corrective actions have taken place.

12 VAC 5-421-750. Reheating for Immediate Service.

3-403.10

Cooked and refrigerated food that is prepared for immediate service in response to an individual consumer order, such as a roast beef sandwich au jus, may be served at any temperature.

12 VAC 5-421-760. Reheating for Hot Holding.*

3-403.11

- A. Except as specified under Subsection B and C and in Subsection E of this section, potentially hazardous food that is cooked, cooled, and reheated for hot holding shall be reheated so that all parts of the food reach at least 165°F (74°C) for 15 seconds.
- B. Except as specified under Subsection C of this section, potentially hazardous food reheated in a microwave oven for hot holding shall be reheated so that all parts of the food reach a temperature of at least 165° F (74° C) and the food is rotated or stirred, covered, and allowed to stand covered 2 minutes after reheating.
- C. Ready-to-eat food taken from a commercially processed, hermetically sealed container, or from an intact package from a food processing plant that is inspected by the food regulatory authority that has jurisdiction over the plant, shall be heated to a temperature of at least $140^{\circ}F$ ($60^{\circ}C$) for hot holding.
- D. Reheating for hot holding shall be done rapidly and the time the food is between the temperature specified under 12 VAC 5-421-820 2 and 165°F (74°C) may not exceed 2 hours.
- E. Remaining unsliced portions of roasts of beef that are cooked as specified under 12 VAC 5-421-700 B may be reheated for hot holding using the oven parameters and minimum time and temperature conditions specified under 12 VAC 5-421-700 B.

When food is held, cooled, and reheated in a food establishment, there is an increased risk from contamination caused by personnel, equipment, procedures, or other factors. If food is held at improper temperatures for enough time, pathogens have the opportunity to multiply to dangerous numbers. Proper reheating provides a major degree of assurance that pathogens will be eliminated. It is especially effective in reducing the numbers of Clostridium perfringens that may grow in meat, poultry, or gravy if these products were improperly held. Vegetative cells of C. perfringens can cause foodborne illness when they grow to high numbers. Although it takes as many as 1 million cells to cause foodborne illness, the generation time for C. perfringens is very short at temperatures just below adequate hot holding. Highly resistant C. perfringens spores will survive cooking and hot holding. If food is abused by being held below adequate hot holding temperatures, spores can germinate to become rapidly multiplying vegetative cells.

Although proper reheating will kill most organisms of concern, some toxins such as that produced by **Staphylococcus aureus**, cannot be inactivated through reheating of the food. It is imperative that food contamination be minimized to avoid this risk.

The potential for growth of pathogenic bacteria is greater in reheated cooked foods than in raw foods. This is because spoilage bacteria, which inhibit the growth of pathogens by competition on raw product, are killed during cooking. Subsequent recontamination will allow pathogens to grow without competition if temperature abuse occurs.

Refer also to the public health reason for § 12 VAC 5-421-710.

Part III

Food

Article 5

Limitation of Growth of Organisms of Public Health Concern

12 VAC 5-421-770. Frozen Food.

3-501.11

Stored frozen foods shall be maintained frozen.

12 VAC 5-421-780. Potentially Hazardous Food, Slacking.

3-501.12

Frozen potentially hazardous food that is slacked to moderate the temperature shall be held:

- 1. Under refrigeration that maintains the food temperature at 41°F (5°C) or less, or at 45°F (7°C) or less as specified under 12 VAC 5-421-820 3 or;
- 2. At any temperature if the food remains frozen.

12 VAC 5-421-790. Thawing.

3-501.13

Except as specified in Subsection D of this section, potentially hazardous food shall be thawed:

- 1. Under refrigeration that maintains the food temperature at $41^{\circ}F$ (5°C) or less, or at $45^{\circ}F$ (7°C) or less as specified under 12 VAC 5-421-820 3 or;
- 2. Completely submerged under running water:
 - a. At a water temperature of 70°F (21°C) or below,
 - b. With sufficient water velocity to agitate and float off loose particles in an overflow, and

- c. For a period of time that does not allow thawed portions of ready-to-eat food to rise above $41^{\circ}F$ (5°C), or $45^{\circ}F$ (7°C) as specified under 12 VAC 5-421-820 3, or
- d. For a period of time that does not allow thawed portions of a raw animal food requiring cooking as specified under 12 VAC 5-421-700 A or B to be above 41°F (5°C), or 45°F (7°C) as specified under 12 VAC 5-421-820 3, for more than 4 hours including:
 - (1) The time the food is exposed to the running water and the time needed for preparation for cooking, or
 - (2) The time it takes under refrigeration to lower the food temperature to $41^{\circ}F$ (5°C), or $45^{\circ}F$ (7°C) as specified under 12 VAC 5-421-820 3;
- 3. As part of a cooking process if the food that is frozen is:
 - a. Cooked as specified under 12 VAC 5-421-700 A or B or 12 VAC 5-421-710, or
 - b. Thawed in a microwave oven and immediately transferred to conventional cooking equipment, with no interruption in the process; or
- 4. Using any procedure if a portion of frozen ready-to-eat food is thawed and prepared for immediate service in response to an individual consumer's order.

Temperature and Time Control

12 VAC 5-421-770 Frozen Food.

12 VAC 5-421-780 Potentially Hazardous Food, Slacking. 12 VAC 5-421-790 Thawing.

Freezing prevents microbial growth in foods, but usually does not destroy all microorganisms. Improper thawing provides an opportunity for surviving bacteria to grow to harmful numbers and/or produce toxins. If the food is then refrozen, significant numbers of bacteria and/or all preformed toxins are preserved.

12 VAC 5-421-800. Cooling.*

3-501.14

- A. Cooked potentially hazardous food shall be cooled:
 - 1. Within 2 hours, from 140°F (60°C) to 70°F (21°C); and

- 2. Within 4 hours, from 70°F (21°C) to 41°F (5°C) or less, or to 45°F (7°C) as specified under 12 VAC 5-421-820 3.
- B. Potentially hazardous food shall be cooled within 4 hours to 41°F (5°C) or less, or to 45°F (7°C) as specified under 12 VAC 5-421-820 3 if prepared from ingredients at ambient temperature, such as reconstituted foods and canned tuna.
- C. Except as specified in Subsection D of this section, a potentially hazardous food received in compliance with laws allowing a temperature above 41°F (5°C) during shipment from the supplier as specified in 12 VAC 5-421-340 B, shall be cooled within 4 hours to 41°F (5°C) or less, or 45°F (7°C) or less as specified under 12 VAC 5-421-820 3.
- D. Shell eggs need not comply with Subsection C of this section if the eggs are placed immediately upon their receipt in refrigerated equipment that is capable of maintaining food at 41°F (5°C) or less, or 45°F (7°C) or less as specified under 12 VAC 5-421-820 3.

Proper cooling requires removing heat from food quickly enough to prevent microbial growth. Excessive time for cooling of potentially hazardous foods has been consistently identified as one of the leading contributing factors to foodborne illness. During extended cooling, potentially hazardous foods are subject to the growth of a variety of pathogenic microorganisms. A longer time near ideal bacterial incubation temperatures, 21°C - 49°C (70°F - 120°F), is to be avoided. If the food is not cooled in accordance with this Code requirement, pathogens may grow to sufficient numbers to cause foodborne illness.

If the cooking step prior to cooling is adequate and no recontamination occurs, all but the spore-forming organisms such as **Clostridium perfringens** or **Bacillus cereus** should be killed or inactivated. However, under poorly monitored conditions, other pathogens such as **Salmonella** may be reintroduced. Thus, cooling requirements have been based on growth characteristics of organisms that grow rapidly under temperature abuse conditions.

A separate method for cooling shell eggs is allowed in food establishments because of the cumulative information that has been gathered about the specific dynamics of the particular pathogen of concern in intact shell eggs. Aside from the recognized need for an integrated approach to the cooling of eggs from farm to table, there are several germane facts that support unique provisions for cooling eggs at retail.

There is only one type of microorganism, pathogenic to humans, which appears to be passed transovarially, i.e., **Salmonella** spp.

Salmonella Enteritidis has been shown to have an extended lag phase in shell eggs due to inhibitory characteristics of the albumen. Research indicates that the organisms are physically located near the exterior of the volk membrane, in contact with the bacteriostatic

components. Growth does not appear until the yolk membrane is weakened by age or physically breached and the yolk nutrients, such as iron, become available to the organisms.

Traditional methods of rapidly cooling eggs after washing by the producer or packer can cause damage to the eggs. The eggs may develop cracks and/or checks because of temperature gradients which could lead to migration through the shell of microorganisms on the surface.

Federal regulations effective August 27, 1999, require shell eggs to be transported and distributed under refrigeration at an ambient temperature not to exceed 45 °F. Packed shell eggs must be labeled indicating that refrigeration is required. Imported shell eggs packed for consumer use are required to include a certification that the eggs, at all times after packing, have been stored and transported at an ambient temperature of no greater than 45 °F.

Shell eggs are allowed longer than 4 hours to cool to the temperature required under the Code provided they are placed immediately after receipt in refrigerated equipment that is capable of maintaining food temperatures as required by the Code. With the newly established federal requirement for eggs to be in an ambient storage and transportation temperature of 45 °F, and with refrigeration of eggs at retail as described above, the overall time that eggs are stored at temperatures that allow the growth of **Salmonella** spp. should be shortened. Upon receiving shell eggs, food establishment operators should maximize the circulation of cooled air in refrigeration units by separating flats, cases, and multiple cartons of eggs.

12 VAC 5-421-810. Cooling Methods.

3-501.15

A. Cooling shall be accomplished in accordance with the time and temperature criteria specified under 12 VAC 5-421-800 by using one or more of the following methods based on the type of food being cooled:

- 1. Placing the food in shallow pans;
- 2. Separating the food into smaller or thinner portions;
- 3. Using rapid cooling equipment;
- 4. Stirring the food in a container placed in an ice water bath;
- 5. Using containers that facilitate heat transfer;
- 6. Adding ice as an ingredient; or

- 7. Other effective methods.
- B. When placed in cooling or cold holding equipment, food containers in which food is being cooled shall be:
 - 1. Arranged in the equipment to provide maximum heat transfer through the container walls; and
 - 2. Loosely covered, or uncovered if protected from overhead contamination as specified under 12 VAC 5-421-610 A 2, during the cooling period to facilitate heat transfer from the surface of the food.

Large food items, such as roasts, turkeys, and large containers of rice or refried beans, take longer to cool because of the mass and volume from which heat must be removed. By reducing the volume of the food in an individual container, the rate of cooling is dramatically increased and opportunity for pathogen growth is minimized. If the hot food container is tightly covered, the rate of heat transfer is reduced, i.e., the time required for cooling and the time the food is exposed to optimal temperatures for bacterial multiplication or toxin production are increased. Alternatives to conventional methods include avoiding the need to cool larger masses by preparing smaller batches closer to periods of service or chilling while stirring hot food in containers within an ice water bath. Commercial refrigeration equipment is designed to hold cold food temperatures, not cool large masses of food. Rapid chilling equipment is designed to cool the food to acceptable temperatures quickly by using very low temperatures and high rates of air circulation.

12 VAC 5-421-820. Potentially Hazardous Food, Hot and Cold Holding.* **3-501.16**

Except during preparation, cooking, or cooling, or when time is used as the public health control as specified under 12 VAC 5-421- 850, potentially hazardous food shall be maintained:

- 1. At 140°F (60°C) or above, except that roasts cooked to a temperature and for a time specified under 12 VAC 5-421-700 B or reheated as specified in 12 VAC 5-421-760 E may be held at a temperature of 130°F (54°C); or
- 2. At 41°F (5°C) or less, except as specified under Subsection C of this section and 12 VAC 5-421-830, 12 VAC 5-421-840, and 12 VAC 5-421-1310.
- 3. At $45^{\circ}F$ (7°C) or between $45^{\circ}F$ (7°C) and $41^{\circ}F$ (5°C) in existing refrigeration equipment that is not capable of maintaining the food at $41^{\circ}F$ (5°C) or less if:
 - a. The equipment is in place and in use in the food establishment; and

b. Within 5 years of the regulatory authority's adoption of these regulations, the equipment is upgraded or replaced to maintain food at a temperature of 41°F (5°C) or less.

Bacterial growth and/or toxin production can occur if potentially hazardous food remains in the temperature "Danger Zone" of 5°C to 60°C (41°F to 140°F) too long. Up to a point, the rate of growth increases with an increase in temperature within this zone. Beyond the upper limit of the optimal temperature range for a particular organism, the rate of growth decreases. Operations requiring heating or cooling of food should be performed as rapidly as possible to avoid the possibility of bacterial growth.

12 VAC 5-421-830. Ready-to-Eat, Potentially Hazardous Food, Date Marking.* **3-501.17**

- A. Except as specified in Subsection E of this section, refrigerated, ready-to-eat, potentially hazardous food prepared and held refrigerated for more than 24 hours in a food establishment shall be clearly marked at the time of preparation to indicate the date by which the food shall be consumed which is, including the day of preparation:
 - 1. 7 calendar days or less from the day that the food is prepared, if the food is maintained at $41^{\circ}F$ (5°C) or less; or
 - 2. 4 calendar days or less from the day the food is prepared, if the food is maintained at 45°F (7°C) or less as specified under 12 VAC 5-421-820 3.
- B. Except as specified in Subsection E of this section, a ready-to-eat, potentially hazardous food prepared in a food establishment and subsequently frozen, shall be clearly marked:
 - 1. When the food is thawed, to indicate that the food shall be consumed within 24 hours; or
 - 2. When the food is placed into the freezer, to indicate the length of time before freezing that the food is held refrigerated and which is, including the day of preparation:
 - a. 7 calendar days or less from the day of preparation, if the food is maintained at $41^{\circ}F$ (5°C) or less, or
 - b. 4 calendar days or less from the day of preparation, if the food is maintained at 45°C (7°C) or less as specified under 12 VAC 5-421-820 3; and
 - 3. When the food is removed from the freezer, to indicate the date by which the food shall be consumed which is:

- a. 7 calendar days or less after the food is removed from the freezer, minus the time before freezing, that the food is held refrigerated if the food is maintained at $41^{\circ}F$ ($5^{\circ}C$) or less before and after freezing, or
- b. 4 calendar days or less after the food is removed from the freezer, minus the time before freezing, that the food is held refrigerated if the food is maintained at 45°C (7°C) or less as specified under 12 VAC 5-421-820 3 before and after freezing.
- C. Except as specified in Subsection E and F of this section, a container of refrigerated, ready-to-eat potentially hazardous food prepared and packaged by a food processing plant shall be clearly marked, at the time the original container is opened in a food establishment, to indicate the date by which the food shall be consumed which is, including the day the original container is opened:
 - 1. 7 calendar days or less after the original container is opened, if the food is maintained at 41°F (5°C) or less; or
 - 2. 4 calendar days or less from the day the original container is opened, if the food is maintained at 45°F (7°C) or less as specified under 12 VAC 5-421-820 3.
- D. Except as specified in Subsection E and F of this section, a container of refrigerated, ready-to-eat, potentially hazardous food prepared and packaged by a food processing plant and subsequently opened and frozen in a food establishment shall be clearly marked:
 - 1. When the food is thawed, to indicate that the food shall be consumed within 24 hours; or
 - 2. To indicate the time between the opening of the original container and freezing that the food is held refrigerated and which is, including the day of opening the original container:
 - a. 7 calendar days or less, after opening the original container if the food is maintained at $41^{\circ}F$ ($5^{\circ}C$) or less, or
 - b. 4 calendar days or less after opening the original container if the food is maintained at 45°F (7°C) or less as specified under 12 VAC 5-421-820 3; and
 - 3. When the food is removed from the freezer, to indicate the date by which the food shall be consumed which is:
 - a. 7 calendar days, minus the time before freezing, that the food is held refrigerated if the food is maintained at $41^{\circ}F$ ($5^{\circ}C$) or less before and after freezing, or

- b. 4 calendar days, minus the time before freezing, that the food is held refrigerated if the food is maintained at $45^{\circ}F$ ($7^{\circ}C$) or less as specified under 12 VAC 5-421-820 3 before and after freezing.
- E. Subsections A-D of this section do not apply to individual meal portions served or repackaged for sale from a bulk container upon a consumer's request.
- F. Subsections C and D of this section do not apply to whole, unsliced portions of a cured and processed product with original casing maintained on the remaining portion, such as bologna, salami, or other sausage in a cellulose casing.
- 12 VAC 5-421-840. Ready-to-Eat, Potentially Hazardous Food, Disposition.* 3-501.18
 - A. A food specified under 12 VAC 5-421-830 A shall be discarded if not consumed within:
 - 1. 7 calendar days from the date of preparation if the food is maintained at 41°F (5°C) or less; or
 - 2. 4 calendar days from the date of preparation if the food is maintained at 45°F (7°C) or less as specified under 12 VAC 5-421-820 3
- B. A food specified under Subsection 12 VAC 5-421-830 B 1 or D 1 shall be discarded if not consumed within 24 hours after thawing.
- C. A food specified under Subsections 12 VAC 5-421-830 B 2 and 3 or D 2 and 3 shall be discarded on or before the most recent date marked on the food container or package if the food is not consumed by that date.
- D. A food specified under 12 VAC 5-421-830 C shall be discarded if not consumed within, including the day of opening the original container:
 - 1. 7 calendar days after the date that the original package is opened in a food establishment if the food is maintained at $41^{\circ}F$ ($5^{\circ}C$) or less; or
 - 2. 4 calendar days after the date that the original package is opened in a food establishment if the food is maintained at 45°F (7°C) or less as specified under 12 VAC 5-421-820 3.
 - E. A food specified under 12 VAC 5-421-830 A, B, C, or D shall be discarded if the food is:
 1. Marked with the date specified under 12 VAC 5-421-830 A, B, C, or D and the food is not consumed before the most recent date expires;

- 2. In a container or package which does not bear a date or time; or
- 3. Inappropriately marked with a date or time that exceeds the date or time specified under 12 VAC 5-421-830 A, B, C, or D.
- F. Refrigerated, ready-to-eat, potentially hazardous food prepared in a food establishment and dispensed through a vending machine with an automatic shut-off control that is activated at a temperature of:
 - 1. 41°F (5°C) shall be discarded if not sold within 7 days; or
 - 2. 45°F (7°C) shall be discarded if not sold within 4 days.
- G. A refrigerated, potentially hazardous, ready-to-eat food ingredient or a portion of a refrigerated, potentially hazardous, ready-to-eat food that is subsequently combined with additional ingredients or portions of food shall retain the date marking of the earliest or first-prepared ingredient or portion and shall be discarded as specified under subsections A-F above.

12 VAC 5-421-850. Time as a Public Health Control.*

3-501.19

- A. Except as specified under subsection B of this section, if time only, rather than time in conjunction with temperature, is used as the public health control for a working supply of potentially hazardous food before cooking, or for ready-to-eat potentially hazardous food that is displayed or held for service for immediate consumption:
 - 1. The food shall be marked or otherwise identified to indicate the time that is 4 hours past the point in time when the food is removed from temperature control;
 - 2. The food shall be cooked and served, served if ready-to-eat, or discarded, within 4 hours from the point in time when the food is removed from temperature control;
 - 3. The food in unmarked containers or packages or marked to exceed a 4 hour limit shall be discarded; and
 - 4. Written procedures shall be maintained in the food establishment and made available to the regulatory authority upon request, that ensure compliance with:
 - a. Subdivision A 1-4 of this subsection, and

b. 12 VAC 5-421-800 for food that is prepared, cooked, and refrigerated before time is used as a public health control.

B. In a food establishment that serves a highly susceptible population, time only, rather than time in conjunction with temperature, may not be used as the public health control for raw eggs.

12 VAC 5-421-830 Ready-to-Eat, Potentially Hazardous Food, Date Marking.*
12 VAC 5-421-840 Ready-to-Eat, Potentially Hazardous Food, Disposition.*
12 VAC 5-421-850 Time as a Public Health Control.*

Refer to Annex 7, Chart 3.

Refrigeration prevents food from becoming a hazard by significantly slowing the growth of most microbes. The growth of some bacteria, such as **Listeria monocytogenes**, is significantly slowed but not stopped by refrigeration. Over a period of time, this and like organisms may increase to hazardous levels in ready-to-eat foods.

The date by which the food must be consumed takes into consideration the differences in growth of **Listeria monocytogenes** at $5^{\circ}C$ ($41^{\circ}F$) and $7^{\circ}C$ ($45^{\circ}F$). Based on a predictive growth curve modeling program for **Listeria monocytogenes**, ready-to-eat, potentially hazardous food may be kept at $5^{\circ}C$ ($41^{\circ}F$) a total of 7 days or at $7^{\circ}C$ ($45^{\circ}F$) a total of 4 days. Therefore, the period of time allowed before consumption is shortened for food in refrigerators incapable of maintaining food at $5^{\circ}C$ ($41^{\circ}F$) but capable of maintaining it at $7^{\circ}C$ ($45^{\circ}F$) or below. Food which is prepared and held, or prepared, frozen, and thawed must be controlled by date marking to ensure its safety based on the total amount of time it was held at refrigeration temperature, and the opportunity for **Listeria monocytogenes** to multiply, before freezing and after thawing. Potentially hazardous refrigerated foods must be consumed or discarded by the expiration date.

Potentially hazardous food may be held without temperature control for short time periods not exceeding four hours because there will be no significant growth or toxin production possible in that limited time.

Recipes in which more than one egg is combined carry an increased risk of illness and possible serious consequences for certain people. It is due to this increased risk, and documented occurrences of foodborne illness and death among highly susceptible populations from temperature-abused raw shell eggs contaminated with **Salmonella Enteritidis**, that the use of time as a public health control in institutional settings is not allowed.

A food establishment shall obtain a variance from the regulatory authority as specified in 12 VAC 5-421-3570 and under 12 VAC 5-421-3580 before smoking food as a method of food preservation rather than as a method of flavor enhancement; curing food; brewing alcoholic beverages; using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement or to render a food so that it is not potentially hazardous; using a reduced oxygen method of packaging food except as specified under 12 VAC 5-421-870 where a barrier to Clostridium botulinum in addition to refrigeration exists; custom processing animals that are for personal use as food and not for sale or service in a food establishment; or preparing food by another method that is determined by the regulatory authority to require a variance.

Specific food processes that require a variance have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The variance requirement is designed to ensure that the proposed method of operation is carried out safely.

12 VAC 5-421-870. Reduced Oxygen Packaging, Criteria.*

3-502.12

- A. Except for a food establishment that obtains a variance as specified under 12 VAC 5-421-860, a food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall ensure that there are at least two barriers in place to control the growth and toxin formation of C. botulinum.
- B. A food establishment that packages food using a reduced oxygen packaging method and Clostridium botulinum is identified as a microbiological hazard in the final packaged form shall have a HACCP plan that contains the information specified under 12 VAC 5-421-3630 D and that:
 - 1. Identifies the food to be packaged;
 - 2. Limits the food packaged to a food that does not support the growth of Clostridium botulinum because it complies with one of the following:
 - a. Has an a_w of 0.91 or less,
 - b. Has a pH of 4.6 or less,
 - c. Is a meat or poultry product cured at a food processing plant regulated by the U.S.D.A. using substances specified in 9 CFR 318.7 Approval of substances for use in the preparation of products and 9 CFR 381.147 Restrictions on the use of substances in poultry products and is received in an intact package, or

- d. Is a food with a high level of competing organisms such as raw meat or raw poultry;
- 3. Specifies methods for maintaining food at 41°F (5°C) or below;
- 4. Describes how the packages shall be prominently and conspicuously labeled on the principal display panel in bold type on a contrasting background, with instructions to:
 - a. Maintain the food at 41°F (5°C) or below, and
 - b. Discard the food if within 14 calendar days of its packaging it is not served for on-premises consumption, or consumed if served or sold for off-premises consumption;
- 5. Limits the shelf life to no more than 14 calendar days from packaging to consumption or the original manufacturer's "sell by" or "use by" date, whichever occurs first;
- 6. Includes operational procedures that:
 - a. Prohibit contacting food with bare hands,
 - b. Identify a designated area and the method by which:
 - (1) Physical barriers or methods of separation of raw foods and ready-to-eat foods minimize cross contamination, and
 - (2) Access to the processing equipment is restricted to responsible trained personnel familiar with the potential hazards of the operation, and
 - c. Delineate cleaning and sanitization procedures for food-contact surfaces; and
- 7. Describes the training program that ensures that the individual responsible for the reduced oxygen packaging operation understands the:
 - a. Concepts required for a safe operation,
 - b. Equipment and facilities, and
 - c. Procedures specified under Subsection A 6 of this section and 12 VAC 5-421-3630 D.

C. Except for fish that is frozen before, during, and after packaging, a food establishment may not package fish using a reduced oxygen packaging method.

A Hazard Analysis Critical Control Point (HACCP) plan is necessary when using reduced oxygen packaging (ROP) processing procedures. A reduced oxygen packaged food that has at least two barriers to the growth and toxin production of **C. botulinum** may be packaged in accordance with the provisions of a HACCP plan. The FDA recommends two barriers be used to ensure the safety of foods when **C. botulinum** is a known hazard in the final packaged form.

An ROP food that has only one barrier to the growth and toxin production of **C. botulinum** may be produced only if the food establishment obtains a variance and produces the food in accordance with the provisions of a HACCP plan. An example of a single barrier would be a food with a natural pH of 4.6 or less. Regardless of whether a variance is required, the primary safety barrier that must be monitored for control is adequate refrigeration. Variance requests related to packaging food using reduced levels of oxygen and having only one barrier to control the growth of **C. botulinum** must be considered with particular caution and scrutiny.

This section does not apply to low acid canned foods produced under 21 CFR Part 108 (Emergency Permit Control) and 21 CFR Part 113 (Thermally Processed Low-Acid Foods) or 21 CFR Part 114 (Acidified Foods) because **C. botulinum** is not a hazard in the final packaged form.

FDA strongly recommends that garlic garlic-in-oil mixtures that are produced in a food establishment have two barriers in place. It is not possible to acidify the oil although the crushed cloves can be acidified. An example of two effective barriers is acidification of crushed garlic cloves and refrigeration of the garlic-in-oil mixture. Acidification means a finished equilibrium pH of 4.6 or less. Garlic-in-water mixtures can be acidified and refrigerated, using a HACCP plan without the necessity of a variance.

Unfrozen raw fish is specifically excluded from ROP because of this product's natural association with **Clostridium botulinum**, Type E, which grows at or above 3°C (38°F). To be adequate, a HACCP plan must identify critical control points that are to be monitored to minimize microbial growth during product packaging and storage.

Earlier FDA guidance regarding the reduced oxygen packaging of cured meat products specified a combination of nitrites, nitrates, and salt that at the time of processing consisted of a concentration of at least 120 mg/L of sodium nitrite and a minimum brine concentration of 3.50%. The Code reflects the fact that various substances, combinations of substances, and resultant concentrations are allowed in CFR administered by USDA. The Code provision also includes the requirement for cured poultry products to meet the CFR.

Shelf-life must be determined considering holding temperatures because some pathogens, including **Listeria monocytogenes**, may be a hazard at refrigeration temperatures. Safe food

that remains frozen from the time it is packaged until prepared for service is considered adequately protected.

Part III

Food

Article 6

Food Identity, Presentation, and On-Premises Labeling (Reserved)

12 VAC 5-421-880.	Reserved.	3-601.11
12 VAC 5-421-890.	Reserved.	3-601.12
12 VAC 5-421-900.	Reserved.	3-602.11
12 VAC 5-421-910.	Reserved.	3-602.12
12 VAC 5-421-920.	Reserved.	3-603.11
12 VAC 5-421-930.	Reserved.	

Part III

Food

Article 7

Contaminated Food

12 VAC 5-421-940. Discarding Unsafe, Adulterated, or Contaminated Food.* **3-701.11**

- A. A food that is unsafe, adulterated, or not from an approved source as specified under 12 VAC 5-421-270 through 330 shall be discarded and rendered unusable.
- B. Ready-to-eat food that may have been contaminated by an employee who has been restricted or excluded as specified under 12 VAC 5-421-90 shall be discarded and rendered unusable.

C. Food that is contaminated by food employees, consumers, or other persons through contact with their hands, bodily discharges, such as nasal or oral discharges, or other means shall be discarded and rendered unusable.

Pathogens may be transmitted from person to person through contaminated food. The potential spread of illness is limited when food is discarded if it may have been contaminated by employees who are infected, or are suspected of being infected, or by any person who otherwise contaminates it.

Part III

Food

Article 8

Special Requirements for Highly Susceptible Populations

12 VAC 5-421-950. Pasteurized Foods, Prohibited Reservice, and Prohibited Food.*

3-801.11

In a food establishment that serves a highly susceptible population:

- 1. Prepackaged juice or a prepackaged beverage containing juice, that bears a warning label as specified in 21 CFR, Section 101.17(g) Food Labeling, may not be served or offered for sale;
- 2. Pasteurized shell eggs or pasteurized liquid, frozen, or dry eggs or egg products shall be substituted for raw shell eggs in the preparation of:
 - a. Foods such as Caesar salad, hollandaise or bearnaise sauce, mayonnaise, and egg-fortified beverages, and
 - b. Except as specified in subsection 5 of this section, recipes in which more than one egg is broken and the eggs are combined;
- 3. Food in an unopened original package may not be re-served; and
- 4. The following foods may not be served or offered for sale in a ready-to-eat form:
 - a. Raw animal foods such as raw fish, raw-marinated fish, raw molluscan shellfish, and steak tartare,

- b. A partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue, and
- c. Raw seed sprouts
- 5. Subsection 2.b of this section does not apply if:
 - a. The raw eggs are combined immediately before cooking for one consumer's serving at a single meal, cooked as specified under Section 12 VAC 5-421-700.A.1, and served immediately, such as an omelet, soufflé, or scrambled eggs;
 - b. The raw eggs are combined as an ingredient immediately before baking and the eggs are thoroughly cooked to a ready-to-eat form, such as a cake, muffin, or bread; or
 - c. The preparation of the food is conducted under a HACCP plan that:
 - 1. Identifies the food to be prepared,
 - 2. Prohibits contacting ready-to-eat food with bare hands,
 - 3. Includes specifications and practices that ensure:
 - (a) Salmonella Enteritidis growth is controlled before and after cooking, and
 - (b) Salmonella Enteritidis is destroyed by cooking the eggs according to the temperature and time specified in 12 VAC 5-421-700.A.2,
 - d. Contains the information specified under 12 VAC 5-421-3630.D including procedures that:
 - (1) Control cross contamination of ready-to-eat food with raw eggs, and
 - (2) Delineate cleaning and sanitization procedures for food-contact surfaces, and
 - e. Describes the training program that ensures that the food employee responsible for the preparation of the food understands the procedures to be used.

Refer to the public health reason for § 12 VAC 5-421-270.

The Code provisions that relate to highly susceptible populations are combined in this section for ease of reference and to add emphasis to special food safety precautions that are necessary to

protect those who are particularly vulnerable to foodborne illness and for whom the implications of such illness can be dire.

As a safeguard for highly susceptible populations from the risk of contracting foodborne illness from juice, prepackaged juice is required to be obtained pasteurized or in a commercially sterile, shelf-stable form in a hermetically sealed container. It is important to note that the definition of "juice" includes puréed fruits and vegetables, which is commonly prepared for service to highly susceptible populations. There are documented cases of foodborne illness throughout the United States that were associated with the consumption of various juice products contaminated with microorganisms such as **Cryptosporidium**, **E. coli** O157:H7, **Salmonella** spp., and **Vibrio cholera**. As new information becomes available, the Food Code will be modified or interim interpretive guidance will be issued regarding foodborne illness interventions for on-site juicing and puréeing.

Salmonella often survives traditional preparation techniques. It survives in a lightly cooked omelet, French toast, stuffed pasta, and meringue pies. In 1986 there was a large multistate outbreak of **Salmonella Enteritidis** traced to stuffed pasta made with raw eggs and labeled "fully cooked." Eggs remain a major source of these infections, causing large outbreaks when they are combined and undercooked as was the case in the 1986 outbreak linked to stuffed pasta. Therefore, special added precautions need to be in place with those most susceptible to foodborne illness.

Operators of food establishments serving highly susceptible populations may wish to discuss buyer specifications with their suppliers. Such specifications could stipulate eggs that are produced only by flocks managed under a **Salmonella Enteritidis** control program that is recognized by a regulatory agency that has animal health jurisdiction. Such programs are designed to reduce the presence of **Salmonella Enteritidis** in raw shell eggs. In any case, the food establishment operator must use adequate time and temperature controls within the establishment to minimize the risk of a foodborne illness outbreak relating to **Salmonella Enteritidis**.

Since 1995, raw seed sprouts have emerged as a recognized source of foodborne illness in the United States. The FDA and CDC have issued health advisories that persons who are at a greater risk for foodborne disease should avoid eating raw alfalfa sprouts until such time as intervention methods are in place to improve the safety of these products. For further information, see the FDA Talk Paper entitled, "Interim Advisory on Alfalfa Sprouts" issued on August 31, 1998 and available on the FDA web site (www.fda.gov). Since this issue continues to be under investigation, FDA recommends that interested persons check the FDA web site periodically for more recent, updated information.

Although the Code's allowance for the Regulatory Authority to grant a variance (refer to §§ 12 VAC 5-421-3630, and 12 VAC 5-421-3750) is applicable to all Code provisions, variance requests related to the preparation of food for highly susceptible populations must be considered with particular caution and scrutiny. With all variances, the hazard(s) must be clearly identified and controlled by a HACCP plan that is instituted in conjunction with a standard operational plan that implements good retail practices. Variances that will impact a highly susceptible population must be considered in light of the fact that such a population is at a significantly higher risk of contracting foodborne illnesses and suffering serious consequences including death from those illnesses, than is the general population.

Subparagraph 12 VAC 5-421-950(E)(3) requires a HACCP plan for the use of raw shell eggs when eggs are combined in food establishments serving highly susceptible populations. A variance is not required since the HACCP plan criteria are specific, prescriptive, and conservative and require a cooking temperature and time to ensure destruction of **Salmonella Enteritidis**.

Part IV

Equipment, Utensils, and Linens

Article 1

Materials for Construction and Repair

12 VAC 5-421-960. Multiuse, characteristics.*

4-101.11

Materials that are used in the construction of utensils and food-contact surfaces of equipment may not allow the migration of deleterious substances or impart colors, odors, or tastes to food and under normal use conditions shall be:

- 1. Safe;
- 2. Durable, corrosion-resistant, and nonabsorbent;^N
- 3. Sufficient in weight and thickness to withstand repeated warewashing; N
- 4. Finished to have a smooth, easily cleanable surface; N and,
- 5. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition. N

Multiuse equipment is subject to deterioration because of its nature, i.e., intended use over an extended period of time. Certain materials allow harmful chemicals to be transferred to the food being prepared which could lead to foodborne illness. In addition, some materials can affect the taste of the food being prepared. Surfaces that are unable to be routinely cleaned and sanitized because of the materials used could harbor foodborne pathogens. Deterioration of the surfaces of equipment such as pitting may inhibit adequate cleaning of the surfaces of equipment, so that food prepared on or in the equipment becomes contaminated.

Inability to effectively wash, rinse and sanitize the surfaces of food equipment may lead to the buildup of pathogenic organisms transmissible through food. Studies regarding the rigor required to remove biofilms from smooth surfaces highlight the need for materials of optimal quality in multiuse equipment.

12 VAC 5-421-970. Cast iron, use limitation.

4-101.12

- A. Except as specified in Subsection B and C of this section, cast iron may not be used for utensils or food-contact surfaces of equipment.
 - B. Cast iron may be used as a surface for cooking.
- C. Cast iron may be used in utensils for serving food if the utensils are used only as part of an uninterrupted process from cooking through service.

Cast iron is an alloy of iron and heavy metals which may leach into food if left in contact with acidic foods for extended periods of time. Heavy metal poisoning has resulted from such situations. The temporary or incidental contact that results from using cast iron as a cooking surface and for dispensing utensils used as part of an uninterrupted, short-term process is acceptable because of the brief contact time involved.

12 VAC 5-421-980. Lead in ceramic, china, and crystal utensils, use limitation. **4-101.13**

Ceramic, china, crystal utensils, and decorative utensils such as hand painted ceramic or china that are used in contact with food shall be lead-free or contain levels of lead not exceeding the limits of the following utensil categories:

Utensil		Maximum Lead
Category	Description	mg/L
Hot Beverage Mugs	Coffee Mugs	0.5
Large Hollowware	Bowls 1.1 L (1.16 qt)	1
Small Hollowware	Bowls < 1.1 L (1.16 qt)	2.0
Flat Utensils	Plates, Saucers	3.0

Historically, lead has been used in the formulation and/or decoration of these types of utensils. Specifically, lead-based paints that were used to decorate the utensils such as color glazes have caused high concentrations of lead to leach into the food they contain.

Lead poisoning continues to be an important public health concern due to the seriousness of associated medical problems. Lead poisoning is particularly harmful to the young and has caused learning disabilities and medical problems among individuals who have consumed high levels. The allowable levels of lead are specific to the type of utensil, based on the average contact time and properties of the foods routinely stored in each item listed.

12 VAC 5-421-990. Copper, use limitation.*

4-101.14

- A. Except as specified in Subsection B of this section, copper and copper alloys such as brass may not be used in contact with a food that has a pH below 6 such as vinegar, fruit juice, or wine or for a fitting or tubing installed between a backflow prevention device and a carbonator.
- B. Copper and copper alloys may be used in contact with beer brewing ingredients that have a pH below 6 in the prefermentation and fermentation steps of a beer brewing operation such as a brewpub or microbrewery.

High concentrations of copper are poisonous and have caused foodborne illness. When copper and copper alloy surfaces contact acidic foods, copper may be leached into the food. Carbon dioxide may be released into a water supply because of an ineffective or nonexistent backflow prevention device between a carbonator and copper plumbing components. The acid that results from mixing water and carbon dioxide leaches copper from the plumbing components and the leachate is then transferred to beverages, causing copper poisoning. Backflow prevention devices constructed of copper and copper alloys can cause, and have resulted in, the leaching of both copper and lead into carbonated beverages.

Brass is an alloy of copper and zinc and contains lead which is used to combine the two elements. Historically, brass has been used for items such as pumps, pipe fitting, and goblets. All 3 constituents are subject to leaching when they contact acidic foods, and food poisoning has resulted from such contact.

The steps in beer brewing include malting, mashing, fermentation, separation of the alcoholic beverage from the mash, and rectification. During mashing, it is essential to lower the pH from its normal 5.8 in order to optimize enzymatic activity. The pH is commonly lowered to 5.1-5.2, but may be adjusted to as low as 3.2. The soluble extract of the mash (wort) is boiled with hops for 1 to $2\frac{1}{2}$ hours or more. After boiling, the wort is cooled, inoculated with brewers yeast, and fermented. The use of copper equipment during the prefermentation and fermentation steps typically result in some leaching of copper.

Because copper is an essential nutrient for yeast growth, low levels of copper are metabolized by the yeast during fermentation. However, studies have shown that copper levels above 0.2 mg/L are toxic or lethal to the yeast. In addition, copper levels as low as 3.5 mg/L have been reported to cause symptoms of copper poisoning in humans. Therefore, the levels of copper necessary for

successful beer fermentation (i.e., below 0.2 mg/L) do not reach a level that would be toxic to humans.

Today, domestic beer brewers typically endeavor to use only stainless steel or stainless steel-lined copper equipment (piping, fermenters, filters, holding tanks, bottling machines, keys, etc.) in contact with beer following the hot brewing steps in the beer making process. Some also use pitch-coated oak vats or glass-lined steel vats following the hot brewing steps. Where copper equipment is not used in beer brewing, it is common practice to add copper (along with zinc) to provide the nutrients essential to the yeast for successful fermentation.

12 VAC 5-421-1000. Galvanized metal, use limitation.*

4-101.15

Galvanized metal may not be used for utensils or food-contact surfaces of equipment that are used in contact with acidic food.

Galvanized means iron or steel coated with zinc, a heavy metal that may be leached from galvanized containers into foods that are high in water content. The risk of leaching increases with increased acidity of foods contacting the galvanized container.

12 VAC 5-421-1010. Sponges, use limitation.

4-101.16

Sponges may not be used in contact with cleaned and sanitized or in-use food-contact surfaces.

Sponges are difficult, if not impossible, to clean once they have been in contact with food particles and contaminants that are found in the use environment. Because of their construction, sponges provide harborage for any number and variety of microbiological organisms, many of which may be pathogenic. Therefore, sponges are to be used only where they will not contaminate cleaned and sanitized or in-use, food-contact surfaces such as for cleaning equipment and utensils before rinsing and sanitizing.

12 VAC 5-421-1020. Lead in pewter alloys, use limitation.

4-101.17

Pewter alloys containing lead in excess of 0.05% may not be used as a food-contact surface.

Pewter refers to a number of silver-gray alloys of tin containing various amounts of antimony, copper, and lead. The same concerns about the leaching of heavy metals and lead that apply to brass, galvanized metals, copper, cast iron, ceramics, and crystal also apply to pewter. As previously stated, the storage of acidic moist foods in pewter containers could result in food poisoning (heavy metal poisoning).

12 VAC 5-421-1030. Lead in solder and flux, use limitation.

4-101.18

Solder and flux containing lead in excess of 0.2% may not be used as a food-contact surface. Solder is a material that is used to join metallic parts and is applied in the melted state to solid metals. Solder may be composed of tin and lead alloys. As mentioned in the public health reasons for §§12 VAC 5-421-970 and 12 VAC 5-421-980, lead has been linked to many health problems especially among the young. Consequently, the amount of lead allowed in food equipment is subject to limitation.

12 VAC 5-421-1040. Wood, use limitation.

4-101.19

- A. Except as specified in Subsection B, C, and D of this section, wood and wood wicker may not be used as a food-contact surface.
 - B. Hard maple or an equivalently hard, close-grained wood may be used for:
 - 1. Cutting boards; cutting blocks; bakers' tables; and utensils such as rolling pins, doughnut dowels, salad bowls, and chopsticks; and
 - 2. Wooden paddles used in confectionery operations for pressure scraping kettles when manually preparing confections at a temperature of 230°F (110°C) or above.
- C. Whole, uncut, raw fruits and vegetables, and nuts in the shell may be kept in the wood shipping containers in which they were received, until the fruits, vegetables, or nuts are used.
- D. If the nature of the food requires removal of rinds, peels, husks, or shells before consumption, the whole, uncut, raw food may be kept in:
 - 1. Untreated wood containers; or
 - 2. Treated wood containers if the containers are treated with a preservative that meets the requirements specified in 21 CFR 178.3800 preservatives for wood.

The limited acceptance of the use of wood as a food-contact surface is determined by the nature of the food and the type of wood used. Moist foods may cause the wood surface to deteriorate and the surface may become difficult to clean. In addition, wood that is treated with preservatives may result in illness due to the migration of the preservative chemicals to the food; therefore, only specific preservatives are allowed.

Multiuse kitchenware such as frying pans, griddles, sauce pans, cookie sheets, and waffle bakers that have a perfluorocarbon resin coating shall be used with nonscoring or nonscratching utensils and cleaning aids.

Perfluorocarbon resin is a tough, nonporous and stable plastic material that gives cookware and bakeware a surface to which foods will not stick and that cleans easily and quickly. FDA has approved the use of this material as safe for food-contact surfaces. The Agency has determined that neither the particles that may chip off nor the fumes given off at high temperatures pose a health hazard. However, because this nonstick finish may be scratched by sharp or rough-edged kitchen tools, the manufacturer's recommendations should be consulted and the use of utensils that may scratch, abrasive scouring pads, or cleaners avoided.

12 VAC 5-421-1060. Nonfood-contact surfaces.

4-101.111

Nonfood-contact surfaces of equipment that are exposed to splash, spillage, or other food soiling or that require frequent cleaning shall be constructed of a corrosion-resistant, nonabsorbent, and smooth material.

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

12 VAC 5-421-1070. Single-Service and Single-Use, characteristics.*

4-102.11

Materials that are used to make single-service and single-use articles:

A. May not:

- 1. Allow the migration of deleterious substances, or
- 2. Impart colors, odors, or tastes to food; N and

B. Shall be:

- 1. Safe, and
- 2. Clean. N

The safety and quality of food can be adversely affected through single service and single use articles that are not constructed of acceptable materials. The migration of components of those materials to food they contact could result in chemical contamination and illness to the consumer. In addition, the use of unacceptable materials could adversely affect the quality of the food because of odors, tastes, and colors transferred to the food.

Part IV

Equipment, Utensils, and Linens

Article 2

Design and Construction

12 VAC 5-421-1080. Equipment and Utensils.

4-201.11

Equipment and utensils shall be designed and constructed to be durable and to retain their characteristic qualities under normal use conditions.

Equipment and utensils must be designed and constructed to be durable and capable of retaining their original characteristics so that such items can continue to fulfill their intended purpose for the duration of their life expectancy and to maintain their easy cleanability. If they can not maintain their original characteristics, they may become difficult to clean, allowing for the harborage of pathogenic microorganisms, insects, and rodents. Equipment and utensils must be designed and constructed so that parts do not break and end up in food as foreign objects or present injury hazards to consumers. A common example of presenting an injury hazard is the tendency for tines of poorly designed single service forks to break during use.

12 VAC 5-421-1090. Food Temperature Measuring Devices.*

4-201.12

Food temperature measuring devices may not have sensors or stems constructed of glass, except that thermometers with glass sensors or stems that are encased in a shatterproof coating such as candy thermometers may be used.

Food temperature measuring devices that have glass sensors or stems present a likelihood that glass will end up in food as a foreign object and create an injury hazard to the consumer. In addition, the contents of the temperature measuring device, e.g., mercury, may contaminate food or utensils.

Multiuse food-contact surfaces shall be:

- 1. Smooth;
- 2. Free of breaks, open seams, cracks, chips, pits, and similar imperfections;
- 3. Free of sharp internal angles, corners, and crevices;
- 4. Finished to have smooth welds and joints; and
- 5. Accessible for cleaning and inspection by one of the following methods:
 - a. Without being disassembled,
 - b. By disassembling without the use of tools, or
 - c. By easy disassembling with the use of handheld tools commonly available to maintenance and cleaning personnel such as screwdrivers, pliers, open-end wrenches, and Allen wrenches.

The purpose of the requirements for multiuse food-contact surfaces is to ensure that such surfaces are capable of being easily cleaned and accessible for cleaning. Food-contact surfaces that do not meet these requirements provide a potential harbor for foodborne pathogenic organisms. Surfaces which have imperfections such as cracks, chips, or pits allow microorganisms to attach and form biofilms. Once established, these biofilms can release pathogens to food. Biofilms are highly resistant to cleaning and sanitizing efforts. The requirement for easy disassembly recognizes the reluctance of food employees to disassemble and clean equipment if the task is difficult or requires the use of special, complicated tools.

12 VAC 5-421-1110. CIP Equipment.

4-202.12

- A. CIP equipment shall meet the characteristics specified under 12 VAC 5-421-1100 and shall be designed and constructed so that:
 - 1. Cleaning and sanitizing solutions circulate throughout a fixed system and contact all interior food-contact surfaces, and
 - 2. The system is self-draining or capable of being completely drained of cleaning and sanitizing solutions; and

B. CIP equipment that is not designed to be disassembled for cleaning shall be designed with inspection access points to ensure that all interior food-contact surfaces throughout the fixed system are being effectively cleaned.

Certain types of equipment are designed to be cleaned in place (CIP) where it is difficult or impractical to disassemble the equipment for cleaning. Because of the closed nature of the system, CIP cleaning must be monitored via access points to ensure that cleaning has been effective throughout the system.

The CIP design must ensure that all food-contact surfaces of the equipment are contacted by the circulating cleaning and sanitizing solutions. Dead spots in the system, i.e., areas which are not contacted by the cleaning and sanitizing solutions, could result in the buildup of food debris and growth of pathogenic microorganisms. There is equal concern that cleaning and sanitizing solutions might be retained in the system, which may result in the inadvertent adulteration of food. Therefore, the CIP system must be self-draining.

12 VAC 5-421-1120. "V" Threads, Use Limitation.

4-202.13

"V" type threads may not be used on food-contact surfaces. This section does not apply to hot oil cooking or filtering equipment.

V-type threads present a surface which is difficult to clean routinely; therefore, they are not allowed on food-contact surfaces. The exception provided for hot oil cooking fryers and filtering systems is based on the high temperatures that are used in this equipment. The high temperature in effect sterilizes the equipment, including debris in the "V" threads.

12 VAC 5-421-1130. Hot Oil Filtering Equipment.

4-202.14

Hot oil filtering equipment shall meet the characteristics specified under 12 VAC 5-421-1100 or 12 VAC 5-421-1110 and shall be readily accessible for filter replacement and cleaning of the filter.

To facilitate and ensure effective cleaning of this equipment, Code requirements, §§ 12 VAC 5-421-1100 and 12 VAC 5-421-1110 must be followed. The filter is designed to keep the oil free of undesired materials and therefore must be readily accessible for replacement. Filtering the oil reduces the likelihood that off-odors, tastes, and possibly toxic compounds may be imparted to food as a result of debris buildup. To ensure that filtering occurs, it is necessary for the filter to be accessible for replacement.

12 VAC 5-421-1140. Can Openers.

4-202.15

Cutting or piercing parts of can openers shall be readily removable for cleaning and for replacement.

Once can openers become pitted or the surface in any way becomes uncleanable, they must be replaced because they can no longer be adequately cleaned and sanitized. Can openers must be designed to facilitate replacement.

12 VAC 5-421-1150. Nonfood-Contact Surfaces.

4-202.16

Nonfood-contact surfaces shall be free of unnecessary ledges, projections, and crevices, and designed and constructed to allow easy cleaning and to facilitate maintenance.

Hard-to-clean areas could result in the attraction and harborage of insects and rodents and allow the growth of foodborne pathogenic microorganisms. Well-designed equipment enhances the ability to keep nonfood-contact surfaces clean.

12 VAC 5-421-1160. Kick Plates, Removable.

4-202.17

Kick plates shall be designed so that the areas behind them are accessible for inspection and cleaning by being:

- 1. Removable by one of the methods specified under Subsections 12 VAC 5-421-1100 E 1 through 3 or capable of being rotated open; and
- 2. Removable or capable of being rotated open without unlocking equipment doors.

The use of kick plates is required to allow access for proper cleaning. If kick plate design and installation does not meet Code requirements, debris could accumulate and create a situation that may attract insects and rodents.

12 VAC 5-421-1170. Ventilation Hood Systems, Filters.

4-202.18

Filters or other grease extracting equipment shall be designed to be readily removable for cleaning and replacement if not designed to be cleaned in place.

12 VAC 5-421-1180. Temperature Measuring Devices, Food.

4-203.11

- A. Food temperature measuring devices that are scaled only in Fahrenheit or dually scaled in Fahrenheit and Celsius shall be scaled in $2^{\circ}F$ increments and accurate to $\pm 2^{\circ}F$ in the intended range of use.
- B. Food temperature measuring devices that are scaled only in Celsius shall be scaled in 1° C increments accurate to $\pm 1^{\circ}$ C in the intended range of use.

The Metric Conversion Act of 1975 (amended 1988) requires that all federal government regulations use the Celsius scale for temperature measurement. The Fahrenheit scale is included in the Code for those jurisdictions using the Fahrenheit scale for temperature measurement.

The small margin of error specified for thermometer accuracy is due to the lack of a large safety margin in the temperature requirements themselves. The accuracy specified for a particular food temperature measuring device is applicable to its entire range of use, that is, from refrigeration through cooking temperatures if the device is intended for such use.

12 VAC 5-421-1190. Temperature Measuring Devices, Ambient Air and Water. **4-203.12**

A. Ambient air and water temperature measuring devices that are scaled in Fahrenheit or dually scaled in Fahrenheit and Celsius and shall be designed to be easily readable and scaled in $3^{\circ}F$ increments and accurate to $\pm 3^{\circ}F$ in the intended range of use.

B. Ambient air and water temperature measuring devices that are scaled only in Celsius shall be scaled in 1.5° C increments and accurate to $\pm 1.5^{\circ}$ C in the intended range of use.

A temperature measuring device used to measure the air temperature in a refrigeration unit is not required to be as accurate as a food thermometer because the unit's temperature fluctuates with repeated opening and closing of the door and because accuracy in measuring internal food temperatures is of more significance.

The Celsius scale is the federally recognized scale based on The Metric Conversion Act of 1975 (amended 1988) which requires the use of metric values. The $\pm 1.5^{\circ}$ C requirement is more stringent than the 3°F previously required since $\pm 1.5^{\circ}$ C is equivalent to $\pm 2.7^{\circ}$ F. The more rigid accuracy results from the practical application of metric equivalents to the temperature gradations of Celsius thermometers.

If Fahrenheit thermometers are used, the $3^{\circ}F$ requirement applies because of the calibrated intervals of Fahrenheit thermometers.

The accuracy specified for a particular air or water temperature measuring device is applicable to its intended range of use. For example, a cold holding unit may have a temperature measuring device that measures from a specified frozen temperature to $20^{\circ}C$ (68°F). The device must be accurate to specifications within that use range.

12 VAC 5-421-1200. Pressure Measuring Devices, Mechanical Warewashing Equipment. 4-203.13

- A. Pressure measuring devices that display the pressures in the water supply line for the fresh hot water sanitizing rinse shall have increments of 1 pounds per square inch (7 kilopascals) or smaller and shall be accurate to \pm 2 pounds per square inch (\pm 14 kilopascals) in the 15-25 pounds per square inch (100-170 kilopascals) range.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

Flow pressure is a very important factor with respect to the efficacy of sanitization. A pressure below the design pressure results in inadequate spray patterns and incomplete coverage of the utensil surfaces to be sanitized. Excessive flow pressure will tend to atomize the water droplets needed to convey heat into a vapor mist that cools before reaching the surfaces to be sanitized.

12 VAC 5-421-1210. Ventilation Hood Systems, Drip Prevention.

4.204.11

Exhaust ventilation hood systems in food preparation and warewashing areas including components such as hoods, fans, guards, and ducting shall be designed to prevent grease or condensation from draining or dripping onto food, equipment, utensils, linens, and single-service and single-use articles.

The dripping of grease or condensation onto food constitutes adulteration and may involve contamination of the food with pathogenic organisms. Equipment, utensils, linens, and single service and single use articles that are subjected to such drippage are no longer clean.

12 VAC 5-421-1220. Equipment Openings, Closures and Deflectors.

- A. A cover or lid for equipment shall overlap the opening and be sloped to drain.
- B. An opening located within the top of a unit of equipment that is designed for use with a cover or lid shall be flanged upward at least two-tenths of an inch (5 millimeters).
- C. Except as specified under Subsection D of this section, fixed piping, temperature measuring devices, rotary shafts, and other parts extending into equipment shall be provided with a watertight joint at the point where the item enters the equipment.
 - D. If a watertight joint is not provided:
 - 1. The piping, temperature measuring devices, rotary shafts, and other parts extending through the openings shall be equipped with an apron designed to deflect condensation, drips, and dust from openings into the food; and

2. The opening shall be flanged as specified under Subsection B of this section.

Equipment openings and covers must be designed to protect stored or prepared food from contaminants and foreign matter that may fall into the food. The requirement for an opening to be flanged upward and for the cover to overlap the opening and be sloped to drain prevents contaminants, especially liquids, from entering the food-contact area.

Some equipment may have parts that extend into the food-contact areas. If these parts are not provided with a watertight joint at the point of entry into the food-contact area, liquids may contaminate the food by adhering to shafts or other parts and running or dripping into the food.

An apron on parts extending into the food-contact area is an acceptable alternative to the watertight seal. If the apron is not properly designed and installed, condensation, drips, and dust may gain access to the food.

12 VAC 5-421-1230. Dispensing Equipment, Protection of Equipment and Food. **4-204.13**

In equipment that dispenses or vends liquid food or ice in unpackaged form:

- 1. The delivery tube, chute, orifice, and splash surfaces directly above the container receiving the food shall be designed in a manner, such as with barriers, baffles, or drip aprons, so that drips from condensation and splash are diverted from the opening of the container receiving the food;
- 2. The delivery tube, chute, and orifice shall be protected from manual contact such as by being recessed;
- 3. The delivery tube or chute and orifice of equipment used to vend liquid food or ice in unpackaged form to self-service consumers shall be designed so that the delivery tube or chute and orifice are protected from dust, insects, rodents, and other contamination by a self-closing door if the equipment is:
 - a. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment, or
 - b. Available for self-service during hours when it is not under the full-time supervision of a food employee; and
- 4. The dispensing equipment actuating lever or mechanism and filling device of consumer self-service beverage dispensing equipment shall be designed to prevent contact with the lip-contact surface of glasses or cups that are refilled.

This requirement is intended to protect both the machine-dispensed, unpackaged, liquid foods and the machine components from contamination. Barriers need to be provided so that the only liquid entering the food container is the liquid intended to be dispensed when the machine's mechanism is activated. Recessing of the machine's components and self-closing doors prevent contamination of machine ports by people, dust, insects, or rodents. If the equipment components become contaminated, the product itself will be exposed to possible contamination.

A direct opening into the food being dispensed allows dust, vermin, and other contaminants access to the food.

12 VAC 5-421-1240. Vending Machine, Vending Stage Closure.

4-204.14

The dispensing compartment of a vending machine including a machine that is designed to vend prepackaged snack food that is not potentially hazardous such as chips, party mixes, and pretzels shall be equipped with a self-closing door or cover if the machine is:

- 1. Located in an outside area that does not otherwise afford the protection of an enclosure against the rain, windblown debris, insects, rodents, and other contaminants that are present in the environment; or
- 2. Available for self-service during hours when it is not under the full-time supervision of a food employee.

Since packaged foods dispensed from vending machines could attract insects and rodents, a self-closing door is required as a barrier to their entrance.

12 VAC 5-421-1250. Bearings and Gear Boxes, Leakproof.

4-204.15

Equipment containing bearings and gears that require lubricants shall be designed and constructed so that the lubricant can not leak, drip, or be forced into food or onto food-contact surfaces.

It is not unusual for food equipment to contain bearings and gears. Lubricants necessary for the operation of these types of equipment could contaminate food or food-contact surfaces if the equipment is not properly designed and constructed.

12 VAC 5-421-1260. Beverage Tubing, Separation.

4-204.16

Beverage tubing and cold-plate beverage cooling devices may not be installed in contact with stored ice. This section does not apply to cold plates that are constructed integrally with an ice storage bin.

Beverage tubing and coldplate cooling devices may result in contamination if they are installed in direct contact with stored ice. Beverage tubing installed in contact with ice may result in condensate and drippage contaminating the ice as the condensate moves down the beverage tubing and ends up in the ice.

The presence of beverage tubing and/or coldplate cooling devices also presents cleaning problems. It may be difficult to adequately clean the ice bin if they are present. Because of the high moisture environment, mold and algae may form on the surface of the ice bins and any tubing or equipment stored in the bins.

12 VAC 5-421-1270. Ice Units, Separation of Drains.

4-204.17

Liquid waste drain lines may not pass through an ice machine or ice storage bin.

Liquid waste drain lines passing through ice machines and storage bins present a risk of contamination due to potential leakage of the waste lines and the possibility that contaminants will gain access to the ice through condensate migrating along the exterior of the lines. Liquid drain lines passing through the ice bin are, themselves, difficult to clean and create other areas that are difficult to clean where they enter the unit as well as where they abut other surfaces. The potential for mold and algal growth in this area is very likely due to the high moisture environment. Molds and algae that form on the drain lines are difficult to remove and present a risk of contamination to the ice stored in the bin.

12 VAC 5-421-1280. Condenser Unit, Separation.

4-204.18

If a condenser unit is an integral component of equipment, the condenser unit shall be separated from the food and food storage space by a dustproof barrier.

A dust-proof barrier between a condenser and food storage areas of equipment protects food and food-contact areas from contamination by dust that is accumulated and blown about as a result of the condenser's operation.

12 VAC 5-421-1290. Can Openers on Vending Machines.

4-204.19

Cutting or piercing parts of can openers on vending machines shall be protected from manual contact, dust, insects, rodents, and other contamination.

Since the cutting or piercing surfaces of a can opener directly contact food in the container being opened, these surfaces must be protected from contamination.

12 VAC 5-421-1300.Molluscan Shellfish Tanks.

- A. Except as specified under Subsection B of this section, molluscan shellfish life support system display tanks may not be used to display shellfish that are offered for human consumption.
- B. Molluscan shellfish life-support system display tanks that are used to store and display shellfish that are offered for human consumption shall be operated and maintained in accordance with a variance granted by the regulatory authority as specified in 12 VAC 5-421-3570 and a HACCP plan that:
 - 1. Is submitted by the permit holder and approved as specified under 12 VAC 5-421-3580; and

2. Ensures that:

- a. Water used with fish other than molluscan shellfish does not flow into the molluscan tank,
- b. The safety and quality of the shellfish as they were received are not compromised by the use of the tank, and
- c. The identity of the source of the shellstock is retained as specified under 12 VAC 5-421-440

Shellfish are filter feeders allowing concentration of pathogenic microorganisms that may be present in the water. Due to the number of shellfish and the limited volume of water used, display tanks may allow concentration of pathogenic viruses and bacteria.

Since many people eat shellfish either raw or lightly cooked, the potential for increased levels of pathogenic microorganisms in shellfish held in display tanks is of concern.

If shellfish stored in molluscan shellfish tanks are offered for consumption, certain safeguards must be in place as specified in a detailed HACCP plan that is approved by the regulatory authority. Opportunities for contamination must be controlled or eliminated.

Procedures must emphasize strict monitoring of the water quality of the tank including the filtering and disinfection system.

12 VAC 5-421-1310. Vending Machines, Automatic Shutoff.*

- A. A machine vending potentially hazardous food shall have an automatic control that prevents the machine from vending food:
 - 1. If there is a power failure, mechanical failure, or other condition that results in an internal machine temperature that can not maintain food temperatures as specified under Part III; and

- 2. If a condition specified under Subsection A 1 of this section occurs, until the machine is serviced and restocked with food that has been maintained at temperatures specified under Part III.
- B. When the automatic shutoff within a machine vending potentially hazardous food is activated:
 - 1. In a refrigerated vending machine, the ambient temperature may not exceed 41°F (5°C) or 45°F (7°C) as specified under 12 VAC 5-421-820 for more than 30 minutes immediately after the machine is filled, serviced, or restocked; or
 - 2. In a hot holding vending machine, the ambient temperature may not be less than 140°F (60°C) for more than 120 minutes immediately after the machine is filled, serviced, or restocked.

Failure to store potentially hazardous food at safe temperatures in a vending machine could result in the growth of pathogenic microorganisms that may result in foodborne illness. The presence of an automatic control that prevents the vending of food if the temperature of the unit exceeds Code requirements precludes the vending of foods that may not be safe.

It is possible and indeed very likely that the temperature of the storage area of a vending machine may exceed Code requirements during the stocking and servicing of the machine. The automatic shut off, commonly referred to as the "public health control", provides a limited amount of time that the ambient temperature of a machine may exceed Code requirements. Strict adherence to the time requirements can limit the growth of pathogenic microorganisms.

12 VAC 5-421-1320. Temperature Measuring Devices.

- A. In a mechanically refrigerated or hot food storage unit, the sensor of a temperature measuring device shall be located to measure the air temperature in the warmest part of a mechanically refrigerated unit and in the coolest part of a hot food storage unit.
- B. Except as specified in Subsection C of this section, cold or hot holding equipment used for potentially hazardous food shall be designed to include and shall be equipped with at least one integral or affixed temperature measuring device that is located to allow easy viewing of the device's temperature display.
- C. Subsection B of this section does not apply to equipment for which the placement of a temperature measuring device is not a practical means for measuring the ambient air surrounding the food because of the design, type, and use of the equipment, such as calrod units, heat lamps, cold plates, bainmaries, steam tables, insulated food transport containers, and salad bars.

D. Temperature measuring devices shall be designed to be easily readable.

E. Food temperature measuring devices and water temperature measuring devices on warewashing machines shall have a numerical scale, printed record, or digital readout in increments no greater than 2°F or 1°C in the intended range of use. However, this subsection shall not apply to home model dishwashers used in bed and breakfast facilities serving 18 or fewer customers.

The placement of the temperature measuring device is important. If the device is placed in the coldest location in the storage unit, it may not be representative of the temperature of the unit. Food could be stored in areas of the unit that exceed Code requirements. Therefore, the temperature measuring device must be placed in a location that is representative of the actual storage temperature of the unit to ensure that all potentially hazardous foods are stored at least at the minimum temperature required in Chapter 3.

A permanent temperature measuring device is required in any unit storing potentially hazardous food because of the potential growth of pathogenic microorganisms should the temperature of the unit exceed Code requirements. In order to facilitate routine monitoring of the unit, the device must be clearly visible.

The exception to requiring a temperature measuring device for the types of equipment listed is primarily due to equipment design and function. It would be difficult and impractical to permanently mount a temperature measuring device on the equipment listed. The futility of attempting to measure the temperature of unconfined air such as with heat lamps and, in some cases, the brief period of time the equipment is used for a given food negate the usefulness of ambient temperature monitoring at that point. In such cases, it would be more practical and accurate to measure the internal temperature of the food.

The importance of maintaining potentially hazardous foods at the specified temperatures requires that temperature measuring devices be easily readable. The inability to accurately read a thermometer could result in food being held at unsafe temperatures.

Temperature measuring devices must be appropriately scaled per Code requirements to ensure accurate readings.

The required incremental gradations are more precise for food measuring devices than for those used to measure ambient temperature because of the significance at a given point in time, i.e., the potential for pathogenic growth, versus the unit's temperature. The food temperature will not necessarily match the ambient temperature of the storage unit; it will depend on many variables including the temperature of the food when it is placed in the unit, the temperature at which the unit is maintained, and the length of time the food is stored in the unit.

12 VAC 5-421-1330. Warewashing Machine, Data Plate Operating Specifications.

4-204.113

- A. A warewashing machine shall be provided with an easily accessible and readable data plate affixed to the machine by the manufacturer that indicates the machine's design and operating specifications including the:
 - 1. Temperatures required for washing, rinsing, and sanitizing;
 - 2. Pressure required for the fresh water sanitizing rinse unless the machine is designed to use only a pumped sanitizing rinse; and
 - 3. Conveyor speed for conveyor machines or cycle time for stationary rack machines.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

The data plate provides the operator with the fundamental information needed to ensure that the machine is effectively washing, rinsing, and sanitizing equipment and utensils. The warewashing machine has been tested, and the information on the data plate represents the parameters that ensure effective operation and sanitization and that need to be monitored.

12 VAC 5-421-1340. Warewashing Machines, Internal Baffles.

4-204.114

- A. Warewashing machine wash and rinse tanks shall be equipped with baffles, curtains, or other means to minimize internal cross contamination of the solutions in wash and rinse tanks.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

The presence of baffles or curtains separating the various operational cycles of a warewashing machine such as washing, rinsing, and sanitizing are designed to reduce the possibility that solutions from one cycle may contaminate solutions in another. The baffles or curtains also prevent food debris from being splashed onto the surface of equipment that has moved to another cycle in the procedure.

- A. A warewashing machine shall be equipped with a temperature measuring device that indicates the temperature of the water:
 - 1. In each wash and rinse tank; and
 - 2. As the water enters the hot water sanitizing final rinse manifold or in the chemical sanitizing solution tank.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

The requirement for the presence of a temperature measuring device in each tank of the warewashing machine is based on the importance of temperature in the sanitization step. In hot water machines, it is critical that minimum temperatures be met at the various cycles so that the cumulative effect of successively rising temperatures causes the surface of the item being washed to reach the required temperature for sanitization. When chemical sanitizers are used, specific minimum temperatures must be met because the effectiveness of chemical sanitizers is directly affected by the temperature of the solution.

- 12 VAC 5-421-1360. Manual Warewashing Equipment, Heaters and Baskets. **4-204.116**
- A. If hot water is used for sanitization in manual warewashing operations, the sanitizing compartment of the sink shall be:
 - 1. Designed with an integral heating device that is capable of maintaining water at a temperature not less than 171°F (77°C); and
 - 2. Provided with a rack or basket to allow complete immersion of equipment and utensils into the hot water.
- B. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

Hot water sanitization is accomplished in water of not less than $77^{\circ}C$ ($170^{\circ}F$) and an integral heating device is necessary to ensure that the minimum temperature is reached.

The rack or basket is required in order to safely handle the equipment and utensils being washed and to ensure immersion. Water at this temperature could result in severe burns to employees operating the equipment.

12 VAC 5-421-1370. Warewashing Machines, Sanitizer Level Indicator.

4-204.117

- A. A warewashing machine that uses a chemical for sanitization and that is installed after adoption of this Chapter by the regulatory authority, shall be equipped with a device that indicates audibly or visually when more chemical sanitizer needs to be added.
- B. Within 5 years of the regulatory authority's adoption of these regulations, existing warewashing equipment shall be upgraded or replaced to meet the requirements of Subsection A.
- C. In lieu of subsections A and B of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.
- 12 VAC 5-421-1380. Warewashing Machines, Flow Pressure Device. **4-204.118**
- A. Warewashing machines that provide a fresh hot water sanitizing rinse shall be equipped with a pressure gauge or similar device such as a transducer that measures and displays the water pressure in the supply line immediately before entering the warewashing machine; and
- B. If the flow pressure measuring device is upstream of the fresh hot water sanitizing rinse control valve, the device shall be mounted in a one-fourth inch or 6.4 millimeter Iron Pipe Size (IPS) valve.
- C. Subsections A and B of this section do not apply to a machine that uses only a pumped or recirculated sanitizing rinse.
- D. Subsections A and B of this section shall not apply to home model dishwashers used in bed and breakfast facilities serving 18 or fewer customers.

Flow pressure is a very important factor impacting the efficacy of sanitization in machines that use fresh hot water at line-pressure as a final sanitization rinse. (See discussion in Public Health Reason for Section 12 VAC 5-421-1200.) It is important that the operator be able to monitor, and the food inspector be able to check, final sanitization rinse pressure as well as machine water temperatures. ANSI/NSF Standard #3, a national voluntary consensus standard for Commercial Spray-Type Dishwashing Machines, specifies that a pressure gauge or similar device be provided on this type machine and such devices are shipped with machines by the manufacturer. Flow pressure devices installed on the upstream side of the control (solenoid) valve are subject to damage and failure due to the water hammer effect caused throughout the dishwashing period each time the control valve closes. The IPS valve provides a ready means for checking line-pressure with an alternative pressure measuring device. A flow pressure device is not required on machines that use only a pumped or recirculated sanitizing rinse since an appropriate pressure is ensured by a pump and is not dependent upon line-pressure.

12 VAC 5-421-1390. Warewashing Sinks and Drainboards, Self-Draining.

4-204.119

Sinks and drainboards of warewashing sinks and machines shall be self-draining.

12 VAC 5-421-1400. Equipment Compartments, Drainage.

4-204.120

Equipment compartments that are subject to accumulation of moisture due to conditions such as condensation, food or beverage drip, or water from melting ice shall be sloped to an outlet that allows complete draining.

12 VAC 5-421-1390 Warewashing Sinks and Drainboards, Self-Draining. 12 VAC 5-421-1400 Equipment Compartments, Drainage.

The draining requirement in equipment components is needed to prevent the pooling of water. Pooled water whether from drainage, condensate, drippage, or melting ice could contain or provide a favorable environment for pathogens and other contaminants.

12 VAC 5-421-1410. Vending Machines, Liquid Waste Products.

4-204.121

- A. Vending machines designed to store beverages that are packaged in containers made from paper products shall be equipped with diversion devices and retention pans or drains for container leakage.
 - B. Vending machines that dispense liquid food in bulk shall be:
 - 1. Provided with an internally mounted waste receptacle for the collection of drip, spillage, overflow, or other internal wastes; and
 - 2. Equipped with an automatic shutoff device that will place the machine out of operation before the waste receptacle overflows.
- C. Shutoff devices specified under Subsection B 2 of this section shall prevent water or liquid food from continuously running if there is a failure of a flow control device in the water or liquid food system or waste accumulation that could lead to overflow of the waste receptacle.

The presence of internal waste containers allows for the collection of liquids that spill within the vending machine. Absence of a waste container or, where required, a shutoff valve which controls the incoming liquids could result in wastes spilling within the machine, causing a condition that attracts insects and rodents and compounds cleaning and maintenance problems

12 VAC 5-421-1420. Case Lot Handling Equipment, Moveability.

Equipment, such as dollies, pallets, racks, and skids used to store and transport large quantities of packaged foods received from a supplier in a cased or overwrapped lot, shall be designed to be moved by hand or by conveniently available equipment such as hand trucks and forklifts.

Proper design of case lot handling equipment facilitates moving case lots for cleaning and for surveillance of insect or rodent activity

12 VAC 5-421-1430. Vending Machine Doors and Openings.

4-204.123

4-204.122

A. Vending machine doors and access opening covers to food and container storage spaces shall be tight-fitting so that the space along the entire interface between the doors or covers and the cabinet of the machine, if the doors or covers are in a closed position, is no greater than one-sixteenth inch or 1.5 millimeters by:

- 1. Being covered with louvers, screens, or materials that provide an equivalent opening of not greater than one-sixteenth inch or 1.5 millimeters. Screening of 12 mesh to 1 inch (12 or more mesh to 2.5 centimeters) meets this requirement;
- 2. Being effectively gasketed;
 - 3. Having interface surfaces that are at least one-half inch wide or 13 millimeters; or
- 4. Jambs or surfaces used to form an L-shaped entry path to the interface.
- B. Vending machine service connection openings through an exterior wall of a machine shall be closed by sealants, clamps, or grommets so that the openings are no larger than 1.5 millimeters or one-sixteenth inch.

The objective of this requirement is to provide a barrier against the entrance into vending machines of insects, rodents, and dust. The maximum size of the openings deters the entrance of common pests

12 VAC 5-421-1440. Food Equipment, Certification and Classification. **4-205.10**

Food equipment that is certified or classified for sanitation by an American National Standards Institute (ANSI)-accredited certification program will be deemed to comply with Articles 1 and 2 of this part.

Under ANSI document CA-1 ANSI Policy and Criteria for Accreditation of Certification Programs, it has been stipulated that:

"For food equipment programs, standards that establish sanitation requirements shall be specified government standards or standards that have been ratified by a public health approval step. ANSI shall verify that this requirement has been met by communicating with appropriate standards developing organizations and governmental public health bodies."

The term certified is used when an item of food equipment has been evaluated against an organization's own standard. The term classified is used when one organization evaluates an item of food equipment against a standard developed by another organization.

Part IV

Equipment, Utensils and Linens

Article 3

Numbers and Capacities

12 VAC 5-421-1450. Cooling, Heating, and Holding Capacities.

4-301.11

Equipment for cooling and heating food, and holding cold and hot food, shall be sufficient in number and capacity and capable of providing food temperatures as specified under Part III.

The ability of equipment to cool, heat, and maintain potentially hazardous foods at Code-required temperatures is critical to food safety. Improper holding and cooking temperatures continue to be major contributing factors to foodborne illness. Therefore, it is very important to have adequate hot or cold holding equipment with enough capacity to meet the heating and cooling demands of the operation.

12 VAC 5-421-1460. Manual Warewashing, Sink Compartment Requirements. 4-301.12

- A. Except as specified in Subsection C of this section, a sink with at least 3 compartments shall be provided for manually washing, rinsing, and sanitizing equipment and utensils.
- B. Sink compartments shall be large enough to accommodate immersion of the largest equipment and utensils. If equipment or utensils are too large for the warewashing sink, a warewashing machine or alternative equipment as specified in Subsection C of this section shall be used.
- C. Alternative manual warewashing equipment may be used when there are special cleaning needs or constraints and its use is approved. Alternative manual warewashing equipment may include:
 - 1. High-pressure detergent sprayers;
 - 2. Low- or line-pressure spray detergent foamers;
 - 3. Other task-specific cleaning equipment;
 - 4. Brushes or other implements;

- 5. 2-compartment sinks as specified under Subsection D and E of this section; or
- 6. Receptacles that substitute for the compartments of a multicompartment sink.
- D. Before a 2-compartment sink is used:
 - 1. The permit holder shall have its use approved; and
 - 2. The nature of warewashing shall be limited to batch operations for cleaning kitchenware such as between cutting one type of raw meat and another or cleanup at the end of a shift, and:
 - a. A limited number of items shall be cleaned,
 - b. The cleaning and sanitizing solutions shall be made up immediately before use and drained immediately after use, and
 - c. A detergent-sanitizer shall be used to sanitize and shall be applied as specified under 12 VAC 5-421-1710, or
 - d. A hot water sanitization immersion step shall be used as specified under 12 VAC 5-421-1860 C.
- E. A 2-compartment sink may not be used for warewashing operations where cleaning and sanitizing solutions are used for a continuous or intermittent flow of kitchenware or tableware in an ongoing warewashing process.
- F. In lieu of subsections A through E of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

The 3 compartment requirement allows for proper execution of the 3-step manual warewashing procedure. If properly used, the 3 compartments reduce the chance of contaminating the sanitizing water and therefore diluting the strength and efficacy of the chemical sanitizer that may be used.

Alternative manual warewashing equipment, allowed under certain circumstances and conditions, must provide for accomplishment of the same 3 steps:

1. Application of cleaners and the removal of soil;

- 2. Removal of any abrasive and removal or dilution of cleaning chemicals; and
- 3. Sanitization.

Refer also to the public health reason for § 12 VAC 5-421-1860.

12 VAC 5-421-1470. Drainboards.

4-301.13

Drainboards, utensil racks, or tables large enough to accommodate all soiled and cleaned items that may accumulate during hours of operation shall be provided for necessary utensil holding before cleaning and after sanitizing.

Drainboards or equivalent equipment are necessary to separate soiled and cleaned items from each other and from the food preparation area in order to preclude contamination of cleaned items and of food.

Drainboards allow for the control of water running off equipment and utensils that have been washed and also allow the operator to properly store washed equipment and utensils while they air-dry.

12 VAC 5-421-1480. Ventilation Hood Systems, Adequacy.

4-301.14

Ventilation hood systems and devices shall be sufficient in number and capacity to prevent grease or condensation from collecting on walls and ceilings.

If a ventilation system is inadequate, grease and condensate may build up on the floors, walls and ceilings of the food establishment, causing an insanitary condition and possible deterioration of the surfaces of walls and ceilings. The accumulation of grease and condensate may contaminate food and food-contact surfaces as well as present a possible fire hazard.

Refer also to the public health reason for § 12 VAC 5-421-1210.

12 VAC 5-421-1490. Clothes Washers and Dryers.

4-301.15

- A. Except as specified in Subsection B of this section, if work clothes or linens are laundered on the premises, a mechanical clothes washer and dryer shall be provided and used.
- B. If on-premises laundering is limited to wiping cloths intended to be used moist, or wiping cloths are air-dried as specified under 12 VAC 5-421-1970, a mechanical clothes washer and dryer need not be provided.

To protect food, soiled work clothes or linens must be efficiently laundered. The only practical way of efficiently laundering work clothes on the premises is with the use of a mechanical washer and dryer.

Refer also to the public health reason for § 12 VAC 5-421-1540.

12 VAC 5-421-1500. Utensils, Consumer Self-Service.

4-302.11

A food dispensing utensil shall be available for each container displayed at a consumer self-service unit such as a buffet or salad bar.

Appropriate serving utensils provided at each container will, among other things, reduce the likelihood of food tasting, use of fingers to serve food, use of fingers to remove the remains of one food on the utensil so that it may be used for another, use of soiled tableware to transfer food, and cross contamination between foods, including a raw food to a cooked potentially hazardous food.

12 VAC 5-421-1510. Food Temperature Measuring Devices.

4-302.12

Food temperature measuring devices shall be provided and readily accessible for use in ensuring attainment and maintenance of food temperatures as specified under Part III.

The presence and accessibility of food temperature measuring devices is critical to the effective monitoring of food temperatures. Proper use of such devices provides the operator or person in charge with important information with which to determine if temperatures should be adjusted or if foods should be discarded.

12 VAC 5-421-1520. Temperature Measuring Devices, Manual Warewashing. **4-302.13**

A. In manual warewashing operations, a temperature measuring device shall be provided and readily accessible for frequently measuring the washing and sanitizing temperatures.

B. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

Water temperature is critical to sanitization in warewashing operations. This is particularly true if the sanitizer being used is hot water. The effectiveness of cleaners and chemical sanitizers is also determined by the temperature of the water used. A temperature measuring device is essential to monitor manual warewashing and ensure sanitization.

12 VAC 5-421-1530. Sanitizing Solutions, Testing Devices.

4-302.14

- A. A test kit or other device that accurately measures the concentration in mg/L (ppm) of sanitizing solutions shall be provided and readily accessible for use.
- B. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

Testing devices to measure the concentration of sanitizing solutions are required for 2 reasons:

- 1. The use of chemical sanitizers requires minimum concentrations of the sanitizer during the final rinse step to ensure sanitization; and
- 2. Too much sanitizer in the final rinse water could be toxic.

Part IV

Equipment, Utensils, and Linens

Article 4

Location and Installation

12 VAC 5-421-1540. Equipment, Clothes Washers and Dryers, and Storage Cabinets, Contamination Prevention. 4-401.11

- A. Except as specified in Subsection B of this section, equipment, cabinets used for the storage of food, or cabinets used to store cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be located:
 - 1. In locker rooms;
 - 2. In toilet rooms or vestibules;
 - 3. In garbage rooms;
 - 4. In mechanical rooms;

- 5. Under sewer lines that are not shielded to intercept potential drips;
- 6. Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed:
- 7. Under open stairwells; or
- 8. Under other sources of contamination.
- B. A storage cabinet used for linens or single-service or single-use articles may be stored in a locker room.
- C. If a mechanical clothes washer or dryer is provided, it shall be located only where there is no exposed food; clean equipment, utensils, and linens; unwrapped single-service and single-use articles; and so that the washer or dryer is protected from contamination.

Food equipment and the food that contacts the equipment must be protected from sources of overhead contamination such as leaking or ruptured water or sewer pipes, dripping condensate, and falling objects. When equipment is installed, it must be situated with consideration of the potential for contamination from such overhead sources.

If a clothes washer and dryer are installed adjacent to exposed food, clean equipment, utensils, linens, and unwrapped single-service and single-use articles, it could result in those items becoming contaminated from soiled laundry. The reverse is also true, i.e., items being laundered could become contaminated from the surrounding area if the washer and dryer are not properly located.

12 VAC 5-421-1550. Fixed Equipment, Spacing or Sealing.

4-402.11

- A. Equipment that is fixed because it is not easily movable shall be installed so that it is:
 - 1. Spaced to allow access for cleaning along the sides, behind, and above the equipment;
 - 2. Spaced from adjoining equipment, walls, and ceilings a distance of not more than one thirty-second inch or 1 millimeter; or
 - 3. Sealed to adjoining equipment or walls, if the equipment is exposed to spillage or seepage.
- B. Table-mounted equipment that is not easily movable shall be installed to allow cleaning of the equipment and areas underneath and around the equipment by being:

- 1. Sealed to the table; or
- 2. Elevated on legs as specified under 12 VAC 5-421-1560 D.

This section is designed to ensure that fixed equipment is installed in a way that:

- 1. Allows accessibility for cleaning on all sides, above, and underneath the units or minimizes the need for cleaning due to closely abutted surfaces;
- 2. Ensures that equipment that is subject to moisture is sealed;
- 3. Prevents the harborage of insects and rodents; and
- 4. Provides accessibility for the monitoring of pests.
- 12 VAC 5-421-1560. Fixed Equipment, Elevation or Sealing.

4-402.12

- A. Except as specified in Subsection B and C of this section, floor-mounted equipment that is not easily movable shall be sealed to the floor or elevated on legs that provide at least a 6 inch (15 centimeter) clearance between the floor and the equipment.
- B. If no part of the floor under the floor-mounted equipment is more than 6 inches (15 centimeters) from the point of cleaning access, the clearance space may be only 4 inches (10 centimeters).
- C. This section does not apply to display shelving units, display refrigeration units, and display freezer units located in the consumer shopping areas of a retail food store, if the floor under the units is maintained clean.
- D. Except as specified in Subsection E of this section, table-mounted equipment that is not easily movable shall be elevated on legs that provide at least a 4 inch (10 centimeter) clearance between the table and the equipment.
 - E. The clearance space between the table and table-mounted equipment may be:
 - 1. 3 inches (7.5 centimeters) if the horizontal distance of the table top under the equipment is no more than 20 inches (50 centimeters) from the point of access for cleaning; or
 - 2. 2 inches (5 centimeters) if the horizontal distance of the table top under the equipment is no more than 3 inches (7.5 centimeters) from the point of access for cleaning.

The inability to adequately or effectively clean areas under equipment could create a situation that may attract insects and rodents and accumulate pathogenic microorganisms that are transmissible through food.

The effectiveness of cleaning is directly affected by the ability to access all areas to clean fixed equipment. It may be necessary to elevate the equipment. When elevating equipment is not feasible or prohibitively expensive, sealing to prevent contamination is required.

The economic impact of the requirement to elevate display units in retail food stores, coupled with the fact that the design, weight, and size of such units are not conducive to casters or legs, led to the exception for certain units located in consumer shopping areas, provided the floor under the units is kept clean. This exception for retail food store display equipment including shelving, refrigeration, and freezer units in the consumer shopping areas requires a rigorous cleaning schedule.

Part IV

Equipment, Utensils, Linens

Article 5

Maintenance and Operation

12 VAC 5-421-1570. Good Repair and Proper Adjustment.

4-501.11

- A. Equipment shall be maintained in a state of repair and condition that meets the requirements specified under Part IV, Articles 1 and 2. Unused or non-functioning equipment shall be removed from the premises.
- B. Equipment components such as doors, seals, hinges, fasteners, and kick plates shall be kept intact, tight, and adjusted in accordance with manufacturer's specifications.
- C. Cutting or piercing parts of can openers shall be kept sharp to minimize the creation of metal fragments that can contaminate food when the container is opened.

Proper maintenance of equipment to manufacturer specifications helps ensure that it will continue to operate as designed. Failure to properly maintain equipment could lead to violations of the associated requirements of the Code that place the health of the consumer at risk. For example, refrigeration units in disrepair may no longer be capable of properly cooling or holding potentially hazardous foods at safe temperatures.

The cutting or piercing parts of can openers may accumulate metal fragments that could lead to food containing foreign objects and, possibly, result in consumer injury.

Adequate cleaning and sanitization of dishes and utensils using a warewashing machine is directly dependent on the exposure time during the wash, rinse, and sanitizing cycles. Failure to meet manufacturer and Code requirements for cycle times could result in failure to clean and sanitize. For example, high temperature machines depend on the buildup of heat on the surface of dishes to accomplish sanitization. If the exposure time during any of the cycles is not met, the surface of the items may not reach the time-temperature parameter required for sanitization. Exposure time is also important in warewashing machines that use a chemical sanitizer since the sanitizer must contact the items long enough for sanitization to occur. In addition, a chemical sanitizer will not sanitize a dirty dish; therefore, the cycle times during the wash and rinse phases are critical to sanitization.

12 VAC 5-421-1580. Cutting Surfaces.

4-501.12

Surfaces such as cutting blocks and boards that are subject to scratching and scoring shall be resurfaced if they can no longer be effectively cleaned and sanitized, or discarded if they are not capable of being resurfaced.

Cutting surfaces such as cutting boards and blocks that become scratched and scored may be difficult to clean and sanitize. As a result, pathogenic microorganisms transmissible through food may build up or accumulate. These microorganisms may be transferred to foods that are prepared on such surfaces.

12 VAC 5-421-1590. Microwave Ovens.

4-501.13

Microwave ovens shall meet the safety standards specified in 21 CFR 1030.10 Microwave ovens.

Failure of microwave ovens to meet the CFR standards could result in human exposure to radiation leakage, resulting in possible medical problems to consumers and employees using the machines.

12 VAC 5-421-1600. Warewashing Equipment, Cleaning Frequency. 4-501.14

A warewashing machine; the compartments of sinks, basins, or other receptacles used for washing and rinsing equipment, utensils, or raw foods, or laundering wiping cloths; and drainboards or other equipment used to substitute for drainboards as specified under 12 VAC 5-421-1470 shall be cleaned:

1. Before use;

- 2. Throughout the day at a frequency necessary to prevent recontamination of equipment and utensils and to ensure that the equipment performs its intended function; and
- 3. If used, at least every 24 hours.

During operation, warewashing equipment is subject to the accumulation of food wastes and other soils or sources of contamination. In order to ensure the proper cleaning and sanitization of equipment and utensils, it is necessary to clean the surface of warewashing equipment before use and periodically throughout the day.

12 VAC 5-421-1610. Warewashing Machines, Manufacturers' Operating Instructions. **4-501.15**

- A. A warewashing machine and its auxiliary components shall be operated in accordance with the machine's data plate and other manufacturer's instructions.
- B. A warewashing machine's conveyor speed or automatic cycle times shall be maintained accurately timed in accordance with manufacturer's specifications.

To ensure properly cleaned and sanitized equipment and utensils, warewashing machines must be operated properly. The manufacturer affixes a data plate to the machine providing vital, detailed instructions about the proper operation of the machine including wash, rinse, and sanitizing cycle times and temperatures which must be achieved.

12 VAC 5-421-1620. Warewashing Sinks, Use Limitation.

4-501.16

- A. A warewashing sink may not be used for handwashing. However, a warewashing sink may be used for handwashing in a bed and breakfast facility serving 18 or fewer customers provided approved dispensers, soap, and single-use paper towels are provided.
- B. If a warewashing sink is used to wash wiping cloths, wash produce, or thaw food, the sink shall be cleaned as specified under 12 VAC 5-421-1600 before and after each time it is used to wash wiping cloths or wash produce or thaw food. Sinks used to wash or thaw food shall be sanitized as specified under Part IV, Article 7 before and after using the sink to wash produce or thaw food.

If the wash sink is used for functions other than warewashing, such as washing wiping cloths or washing and thawing foods, contamination of equipment and utensils could occur.

12 VAC 5-421-1630. Warewashing Equipment, Cleaning Agents.

4-501.17

When used for warewashing, the wash compartment of a sink, mechanical warewasher, or wash receptacle of alternative manual warewashing equipment as specified in 12 VAC 5-421-1460 C, shall

contain a wash solution of soap, detergent, acid cleaner, alkaline cleaner, degreaser, abrasive cleaner, or other cleaning agent according to the cleaning agent manufacturer's label instructions.

Failure to use detergents or cleaners in accordance with the manufacturer's label instructions could create safety concerns for the employee and consumer. For example, employees could suffer chemical burns, and chemical residues could find their way into food if detergents or cleaners are used carelessly.

Equipment or utensils may not be cleaned if inappropriate or insufficient amounts of cleaners or detergents are used.

12 VAC 5-421-1640. Warewashing Equipment, Clean Solutions.

4-501.18

A. The wash, rinse, and sanitize solutions shall be maintained clean.

B. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

Failure to maintain clean wash, rinse, and sanitizing solutions adversely affects the warewashing operation. Equipment and utensils may not be sanitized, resulting in subsequent contamination of food.

12 VAC 5-421-1650. Manual Warewashing Equipment, Wash Solution Temperature. **4-501.19**

The temperature of the wash solution in manual warewashing equipment shall be maintained at not less than 110°F (43°C) or the temperature specified on the cleaning agent manufacturer's label instructions.

The wash solution temperature required in the Code is essential for removing organic matter. If the temperature is below 110°F, the performance of the detergent may be adversely affected, e.g., animal fats that may be present on the dirty dishes would not be dissolved.

12 VAC 5-421-1660. Mechanical Warewashing Equipment, Wash Solution Temperature.

4-501.110

A. The temperature of the wash solution in spray type warewashers that use hot water to sanitize may not be less than:

1. For a stationary rack, single temperature machine, 165°F (74°C);

- 2. For a stationary rack, dual temperature machine, 150°F (66°C);
- 3. For a single tank, conveyor, dual temperature machine, 160°F (71°C); or
- 4. For a multitank, conveyor, multitemperature machine, 150°F (66°C).
- B. The temperature of the wash solution in spray-type warewashers that use chemicals to sanitize may not be less than 120°F (49°C).
- C. In lieu of subsection B of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

12 VAC 5-421-1670. Manual Warewashing Equipment, Hot Water Sanitization Temperatures.* 4-501.111

- A. If immersion in hot water is used for sanitizing in a manual operation, the temperature of the water shall be maintained at 171°F (77°C) or above.
- B. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

The wash solution temperature in mechanical warewashing equipment is critical to proper operation. The chemicals used may not adequately perform their function if the temperature is too low. Therefore, the manufacturer's instructions must be followed. The temperatures vary according to the specific equipment being used.

- 12 VAC 5-421-1680. Mechanical Warewashing Equipment, Hot Water Sanitization Temperatures.
- A. Except as specified in Subsection B of this section, in a mechanical operation, the temperature of the fresh hot water sanitizing rinse as it enters the manifold may not be more than 194°F (90°C), or less than:
 - 1. For a stationary rack, single temperature machine, 165°F (74°C); or

- 2. For all other machines, 180°F (82°C).
- B. The maximum temperature specified under Subsection A of this section, does not apply to the high pressure and temperature systems with wand-type, hand-held, spraying devices used for the inplace cleaning and sanitizing of equipment such as meat saws.
- C. In lieu of subsection B of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

If the temperature of the hot water delivered to the warewasher manifold is inadequate to effect sanitization, surviving pathogenic organisms could contaminate equipment and utensils.

12 VAC 5-421-1690. Mechanical Warewashing Equipment, Sanitization Pressure. 4-501.113

A. The flow pressure of the fresh hot water sanitizing rinse in a warewashing machine may not be less than 15 pounds per square inch (100 kilopascals) or more than 25 pounds per square inch (170 kilopascals) as measured in the water line immediately downstream or upstream from the fresh hot water sanitizing rinse control valve.

B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

If the flow pressure of the final sanitizing rinse is less than that required, dispersion of the sanitizing solution may be inadequate to reach all surfaces of equipment or utensils.

12 VAC 5-421-1700. Manual and Mechanical Warewashing Equipment, Chemical Sanitization - Temperature, pH, Concentration, and Hardness.* 4-501.114

- A. A chemical sanitizer used in a sanitizing solution for a manual or mechanical operation at exposure times specified under 12 VAC 5-421-1900 C shall be listed in 21 CFR 178.1010 Sanitizing solutions, shall be used in accordance with the EPA-approved manufacturer's label use instructions, and shall be used as follows:
- 1. A chlorine solution shall have a minimum temperature based on the concentration and pH of the solution as listed in the following chart;

Minimum	Minimum	
Concentration	Temperature	
mg/L (ppm)	pH 10 or	pH 8 or
	less	less
	°F (°C)	°F (°C)
25	120 (49)	120 (49)
50	100 (38)	75 (24)
100	55 (13)	55 (13)

2. An iodine solution shall have a:

- a. Minimum temperature of 75°F (24°C),
- b. pH of 5.0 or less or a pH no higher than the level for which the manufacturer specifies the solution is effective, and
- c. Concentration between 12.5 mg/L (ppm) and 25 mg/L (ppm);
- 3. A quaternary ammonium compound solution shall:
 - a. Have a minimum temperature of 75°F (24°C),
 - b. Have a concentration as specified under 12 VAC 5-421-3380 and as indicated by the manufacturer's use directions included in the labeling, and
 - c. Be used only in water with 500 mg/L hardness or less or in water having a hardness no greater than specified by the manufacturer's label;
- 4. If another solution of a chemical specified under Subsection 1 through 3 of this section is used, the permit holder shall demonstrate to the regulatory authority that the solution achieves sanitization and the use of the solution shall be approved; or
- 5. If a chemical sanitizer other than chlorine, iodine, or a quaternary ammonium compound is used, it shall be applied in accordance with the manufacturer's use directions included in the labeling.

- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.
- C. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) use for no other purpose.

The effectiveness of chemical sanitizers can be directly affected by the temperature, pH, concentration of the sanitizer solution used, and hardness of the water. All sanitizers approved for use under 21 CFR 178.1010 must be used under water conditions stated on the label to ensure efficacy. Therefore, it is critical to sanitization that the sanitizers are used properly and the solutions meet the minimum standards required in the Code.

12 VAC 5-421-1710. Manual Warewashing Equipment, Chemical Sanitization Using Detergent-Sanitizers. 4-501.115

- A. If a detergent-sanitizer is used to sanitize in a cleaning and sanitizing procedure where there is no distinct water rinse between the washing and sanitizing steps, the agent applied in the sanitizing step shall be the same detergent-sanitizer that is used in the washing step.
- B. In lieu of subsection A of this section, the manual cleaning and drying of equipment and utensils in bed and breakfast facilities serving 18 or fewer customers shall include, as a minimum, thorough washing with adequate soap or detergent, thorough rinsing, and drying before storage or use. Drying may be by a clean towel(s) used for no other purpose.

Some chemical sanitizers are not compatible with detergents when a 2 compartment operation is used. When using a sanitizer that is different from the detergent-sanitizer of the wash compartment, the sanitizer may be inhibited by carry-over, resulting in inadequate sanitization.

12 VAC 5-421-1720. Warewashing Equipment, Determining Chemical Sanitizer Concentration. 4-501.116

- A. Concentration of the sanitizing solution shall be accurately determined by using a test kit or other device.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

The effectiveness of chemical sanitizers is determined primarily by the concentration and pH of the sanitizer solution. Therefore, a test kit is necessary to accurately determine the concentration of the chemical sanitizer solution.

12 VAC 5-421-1730. Good Repair and Calibration.

4-502.11

- A. Utensils shall be maintained in a state of repair or condition that complies with the requirements specified under Part IV, Articles 1 and 2 or shall be discarded.
- B. Food temperature measuring devices shall be calibrated in accordance with manufacturer's specifications as necessary to ensure their accuracy.
- C. Ambient air temperature, water pressure, and water temperature measuring devices shall be maintained in good repair and be accurate within the intended range of use. However, this subsection does not apply to home model dishwashers used in bed and breakfast facilities serving 18 or fewer customers.

A utensil or food temperature measuring device can act as a source of contamination to the food it contacts if it is not maintained in good repair. Also, if temperature or pressure measuring devices are not maintained in good repair, the accuracy of the readings is questionable. Consequently, a temperature problem may not be detected, or conversely, a corrective action may be needlessly taken.

12 VAC 5-421-1740. Single-Service and Single-Use Articles, Required Use.* **4-502.12**

A food establishment without facilities specified under Part IV, Articles 6 and 7 for cleaning and sanitizing kitchenware and tableware shall provide only single-use kitchenware, single-service articles, and single-use articles for use by food employees and single-service articles for use by consumers.

In situations in which the reuse of multiuse items could result in foodborne illness to consumers, single-service and single-use articles must be used to ensure safety.

- 12 VAC 5-421-1750. Single-Service and Single-Use Articles, Use Limitation. **4-502.13**
 - A. Single-service and single-use articles may not be reused.
- B. The bulk milk container dispensing tube shall be cut on the diagonal leaving no more than one inch protruding from the chilled dispensing head.

Articles that are not constructed of multiuse materials may not be reused as they are unable to withstand the rigors of multiple uses, including the ability to be subjected to repeated washing, rinsing, and sanitizing.

12 VAC 5-421-1760. Shells, Use Limitation.

4-502.14

Mollusk and crustacea shells may not be used more than once as serving containers.

Mollusk and crustacea shells do not meet the Code requirements for multiuse utensils. Therefore, such shells may be used only once as serving containers.

Refer also to the public health reason for § 12 VAC 5-421-1750.

Part IV

Equipment, Utensils, and Linens

Article 6

Cleaning of Equipment and Utensils

12 VAC 5-421-1770. Equipment, Food-Contact Surfaces, Nonfood-Contact Surfaces, and Utensils.*

- A. Equipment food-contact surfaces and utensils shall be clean to sight and touch.
- B. The food-contact surfaces of cooking equipment and pans shall be kept free of encrusted grease deposits and other soil accumulations. N
- C. Nonfood-contact surfaces of equipment shall be kept free of an accumulation of dust, dirt, food residue, and other debris. $^{\rm N}$

The objective of cleaning focuses on the need to remove organic matter from food-contact surfaces so that sanitization can occur and to remove soil from nonfood contact surfaces so that pathogenic microorganisms will not be allowed to accumulate and insects and rodents will not be attracted.

12 VAC 5-421-1780. Equipment Food-Contact Surfaces and Utensils.*

4-602.11

A. Equipment food-contact surfaces and utensils shall be cleaned:

- 1. Except as specified in Subsection B of this section, before each use with a different type of raw animal food such as beef, fish, lamb, pork, or poultry;
- 2. Each time there is a change from working with raw foods to working with ready-to-eat foods;
- 3. Between uses with raw fruits and vegetables and with potentially hazardous food;
- 4. Before using or storing a food temperature measuring device; and
- 5. At any time during the operation when contamination may have occurred.
- B. Subsection A 1 of this section does not apply if the food contact surface or utensil is in contact with a succession of different raw animal foods each requiring a higher cooking temperature as specified under Section 12 VAC 5-421-700 than the previous food, such as preparing raw fish followed by cutting raw poultry on the same cutting board.
- C. Except as specified in Subsection D of this section, if used with potentially hazardous food, equipment food-contact surfaces and utensils shall be cleaned throughout the day at least every 4 hours.
- D. Surfaces of utensils and equipment contacting potentially hazardous food may be cleaned less frequently than every 4 hours if:
 - 1. In storage, containers of potentially hazardous food and their contents are maintained at temperatures specified under Part III and the containers are cleaned when they are empty;
 - 2. Utensils and equipment are used to prepare food in a refrigerated room or area that is maintained at one of the temperatures in the following chart and
 - a. The utensils and equipment are cleaned at the frequency in the following chart that corresponds to the temperature:

Temperature	Cleaning Frequency
41°F (5.0°C) or less	24 hours
>41°F - 45°F	20 hours
(>5.0°C - 7.2°C)	
>45°F - 50°F	16 hours
(>7.2°C - 10.0°C)	
>50°F - 55°F	10 hours
(>10.0°C - 12.8°C)	

; and

- b. The cleaning frequency based on the ambient temperature of the refrigerated room or area is documented in the food establishment.
- 3. Containers in serving situations such as salad bars, delis, and cafeteria lines hold ready-toeat potentially hazardous food that is maintained at the temperatures specified under Part III, are intermittently combined with additional supplies of the same food that is at the required temperature, and the containers are cleaned at least every 24 hours;
- 4. Temperature measuring devices are maintained in contact with food, such as when left in a container of deli food or in a roast, held at temperatures specified under Part III;
- 5. Equipment is used for storage of packaged or unpackaged food such as a reach-in refrigerator and the equipment is cleaned at a frequency necessary to preclude accumulation of soil residues; or
- 6. The cleaning schedule is approved based on consideration of:
 - a. Characteristics of the equipment and its use,
 - b. The type of food involved,
 - c. The amount of food residue accumulation, and
 - d. The temperature at which the food is maintained during the operation and the potential for the rapid and progressive multiplication of pathogenic or toxigenic microorganisms that are capable of causing foodborne disease.
- 7. In-use utensils are intermittently stored in a container of water in which the water is maintained at 140°F (60°C) or more and the utensils and container are cleaned at least every 24 hours or at a frequency necessary to preclude accumulation of soil residues.
- E. Except when dry cleaning methods are used as specified under 12 VAC 5-421-1810, surfaces of utensils and equipment contacting food that is not potentially hazardous shall be cleaned:
 - 1. At any time when contamination may have occurred;

- 2. At least every 24 hours for iced tea dispensers and consumer self-service utensils such as tongs, scoops, or ladles;
- 3. Before restocking consumer self-service equipment and utensils such as condiment dispensers and display containers;
- 4. Equipment such as ice bins and beverage dispensing nozzles and enclosed components of equipment such as ice makers, beverage dispensing lines or tubes, coffee bean grinders, and water vending equipment:
 - a. At a frequency specified by the manufacturer, or
 - b. Absent manufacturer specifications, at a frequency necessary to preclude accumulation of soil or mold.

Microorganisms may be transmitted from a food to other foods by utensils, cutting boards, thermometers, or other food-contact surfaces. Food-contact surfaces and equipment used for potentially hazardous foods should be cleaned as needed throughout the day but must be cleaned no less than every 4 hours to prevent the growth of microorganisms on those surfaces. Refrigeration temperatures slow down the generation time of bacterial pathogens, making it unnecessary to clean every four hours. However, the time period between cleaning equipment and utensils may not exceed 24 hours. A time-temperature chart is provided in Subparagraph 12 VAC 5-421-1780(D)(2) to accommodate operations that use equipment and utensils in a refrigerated room or area that maintains a temperature between 41°F or less and 55°F.

Surfaces of utensils and equipment contacting food that is not potentially hazardous such as iced tea dispensers, carbonated beverage dispenser nozzles, beverage dispensing circuits or lines, water vending equipment, coffee bean grinders, ice makers, and ice bins must be cleaned on a routine basis to prevent the development of slime, mold, or soil residues that may contribute to an accumulation of microorganisms. Some equipment manufacturers and industry associations, e.g., within the tea industry, develop guidelines for regular cleaning and sanitizing of equipment. If the manufacturer does not provide cleaning specifications for food-contact surfaces of equipment that are not readily visible, the person in charge should develop a cleaning regimen that is based on the soil that may accumulate in those particular items of equipment.

12 VAC 5-421-1790. Cooking and Baking Equipment.

4-602.12

- A. The food-contact surfaces of in-use cooking and baking equipment shall be cleaned at least every 24 hours. This section does not apply to hot oil cooking and filtering equipment if it is cleaned as specified in Subsection 12 VAC 5-421-1780 D 6.
- B. The cavities and door seals of microwave ovens shall be cleaned at least every 24 hours by using the manufacturer's recommended cleaning procedure.

Food-contact surfaces of cooking equipment must be cleaned to prevent encrustations that may impede heat transfer necessary to adequately cook food. Encrusted equipment may also serve as an insect attractant when not in use. Because of the nature of the equipment, it may not be necessary to clean cooking equipment as frequently as the equipment specified in § 12 VAC 5-421-1780.

12 VAC 5-421-1800. Nonfood-Contact Surfaces.

4-602.13

Nonfood-contact surfaces of equipment shall be cleaned at a frequency necessary to preclude accumulation of soil residues.

The presence of food debris or dirt on nonfood contact surfaces may provide a suitable environment for the growth of microorganisms which employees may inadvertently transfer to food. If these areas are not kept clean, they may also provide harborage for insects, rodents, and other pests.

12 VAC 5-421-1810. Dry Cleaning.

4-603.11

- A. If used, dry cleaning methods such as brushing, scraping, and vacuuming shall contact only surfaces that are soiled with dry food residues that are not potentially hazardous.
- B. Cleaning equipment used in dry cleaning food-contact surfaces may not be used for any other purpose.

Dry cleaning methods are indicated in only a few operations, which are limited to dry foods that are not potentially hazardous. Under some circumstances, attempts at wet cleaning may create microbiological concerns.

12 VAC 5-421-1820. Precleaning.

4-603.12

- A. Food debris on equipment and utensils shall be scrapped over a waste disposal unit, scupper, or garbage receptacle or shall be removed in a warewashing machine with a prewash cycle.
- B. If necessary for effective cleaning, utensils and equipment shall be preflushed, presoaked, or scrubbed with abrasives.

Precleaning of utensils, dishes, and food equipment allows for the removal of grease and food debris to facilitate the cleaning action of the detergent. Depending upon the condition of the surface to be cleaned, detergent alone may not be sufficient to loosen soil for cleaning. Heavily soiled surfaces may need to be presoaked or scrubbed with an abrasive.

12 VAC 5-421-1830. Loading of Soiled Items, Warewashing Machines.

4-603.13

Soiled items to be cleaned in a warewashing machine shall be loaded into racks, trays, or baskets or onto conveyors in a position that:

- 1. Exposes the items to the unobstructed spray from all cycles; and
- 2. Allows the items to drain.

Items to be washed in a warewashing machine must receive unobstructed exposure to the spray to ensure adequate cleaning. Items which are stacked or trays which are heavily loaded with silverware cannot receive complete distribution of detergent, water, or sanitizer and cannot be considered to be clean.

12 VAC 5-421-1840. Wet Cleaning.

4-603.14

- A. Equipment food-contact surfaces and utensils shall be effectively washed to remove or completely loosen soils by using the manual or mechanical means necessary such as the application of detergents containing wetting agents and emulsifiers; acid, alkaline, or abrasive cleaners; hot water; brushes; scouring pads; high-pressure sprays; or ultrasonic devices.
- B. The washing procedures selected shall be based on the type and purpose of the equipment or utensil, and on the type of soil to be removed.

Because of the variety of cleaning agents available and the many different types of soil to be removed it is not possible to recommend one cleaning agent to fit all situations. Each of the different types of cleaners works best under different conditions (i.e., some work best on grease, some work best in warm water, others work best in hot water). The specific chemical selected should be compatible with any other chemicals to be used in the operation such as a sanitizer or drying agent.

12 VAC 5-421-1850. Washing, Procedures for Alternative Manual Warewashing Equipment. **4-603.15**

If washing in sink compartments or a warewashing machine is impractical such as when the equipment is fixed or the utensils are too large, washing shall be done by using alternative manual warewashing equipment as specified in 12 VAC 5-421-1460 C in accordance with the following procedures:

- 1. Equipment shall be disassembled as necessary to allow access of the detergent solution to all parts;
- 2. Equipment components and utensils shall be scrapped or rough cleaned to remove food particle accumulation; and
- 3. Equipment and utensils shall be washed as specified under 12 VAC 5-421-1840 A.

Some pieces of equipment are too large (or fixed) to be cleaned in a sink. Nonetheless, cleaning of such equipment requires the application of cleaners for the removal of soil and rinsing for the removal of abrasive and cleaning chemicals, followed by sanitization.

12 VAC 5-421-1860. Rinsing Procedures.

4-603.16

Washed utensils and equipment shall be rinsed so that abrasives are removed and cleaning chemicals are removed or diluted through the use of water or a detergent-sanitizer solution by using one of the following procedures:

- 1. Use of a distinct, separate water rinse after washing and before sanitizing if using:
 - a. A 3-compartment sink,
 - b. Alternative manual warewashing equipment equivalent to a 3-compartment sink as specified in 12 VAC 5-421-1460 C, or
 - c. A 3-step washing, rinsing, and sanitizing procedure in a warewashing system for CIP equipment;
- 2. Use of a detergent-sanitizer as specified under 12 VAC 5-421-1710 if using:
 - a. Alternative warewashing equipment as specified in 12 VAC 5-421-1460 C that is approved for use with a detergent-sanitizer, or
 - b. A warewashing system for CIP equipment;
- 3. Use of a nondistinct water rinse that is integrated in the hot water sanitization immersion step of a 2-compartment sink operation;

- 4. If using a warewashing machine that does not recycle the sanitizing solution as specified under Subsection E of this section, or alternative manual warewashing equipment such as sprayers, use of a nondistinct water rinse that is:
 - a. Integrated in the application of the sanitizing solution, and
 - b. Wasted immediately after each application; or
- 5. If using a warewashing machine that recycles the sanitizing solution for use in the next wash cycle, use of a nondistinct water rinse that is integrated in the application of the sanitizing solution.

It is important to rinse off detergents, abrasive, and food debris after the wash step to avoid diluting or inactivating the sanitizer.

12 VAC 5-421-1870. Returnables, Cleaning for Refilling.*

4-603.17

- A. Except as specified in Subsection B and C of this section, returned empty containers intended for cleaning and refilling with food shall be cleaned and refilled in a regulated food processing plant.
 - B. A food-specific container for beverages may be refilled at a food establishment if:
 - 1. Only a beverage that is not a potentially hazardous food is used as specified under 12 VAC 5-421-600 A;
 - 2. The design of the container and of the rinsing equipment and the nature of the beverage, when considered together, allow effective cleaning at home or in the food establishment;
 - 3. Facilities for rinsing before refilling returned containers with fresh, hot water that is under pressure and not recirculated are provided as part of the dispensing system;
 - 4. The consumer-owned container returned to the food establishment for refilling is refilled for sale or service only to the same consumer; and
 - 5. The container is refilled by: an employee of the food establishment, or the owner of the container if the beverage system includes a contamination-free transfer process that can not be bypassed by the container owner.
- C. Consumer-owned containers that are not food-specific may be filled at a water vending machine or system.

The refilling of consumer-owned beverage containers introduces the possibility of contamination of the filling equipment or product by improperly cleaned containers or the improper operation of the equipment. To prevent this contamination and possible health hazards to the consumer, the refilling of consumer-owned containers is limited to beverages that are not potentially hazardous. Equipment must be designed to prevent the contamination of the equipment and means must be provided to clean the containers at the facility.

Part IV

Equipment, Utensils, and Linens

Article 7

Sanitization of Equipment and Utensils

12 VAC 5-421-1880. Food-Contact Surfaces and Utensils.

4-701.10

- A. Equipment food-contact surfaces and utensils shall be sanitized.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

Effective sanitization procedures destroy organisms of public health importance that may be present on wiping cloths, food equipment, or utensils after cleaning, or which have been introduced into the rinse solution. It is important that surfaces be clean before being sanitized to allow the sanitizer to achieve its maximum benefit.

12 VAC 5-421-1890. Before Use After Cleaning.*

4-702.11

- A. Utensils and food-contact surfaces of equipment shall be sanitized before use after cleaning.
- B. In lieu of subsection A of this section, home model dishwashers may be used in lieu of manual cleaning and drying of utensils in bed and breakfast facilities serving 18 or fewer customers.

Sanitization is accomplished after the warewashing steps of cleaning and rinsing so that utensils and food-contact surfaces are sanitized before coming in contact with food and before use.

12 VAC 5-421-1900. Hot Water and Chemical.*

4-703.11

- A. After being cleaned, equipment food-contact surfaces and utensils shall be sanitized in:
- 1. Hot water manual operations by immersion for at least 30 seconds as specified under 12 VAC 5-421-1670;
- 2. Hot water mechanical operations by being cycled through equipment that is set up as specified under 12 VAC 5-421-1610, and 12 VAC 5-421-1680, and 12 VAC 5-421-1690 and achieving a utensil surface temperature of 160°F (71°C) as measured by an irreversible registering temperature indicator; or
- 3. Chemical manual or mechanical operations, including the application of sanitizing chemicals by immersion, manual swabbing, brushing, or pressure spraying methods, using a solution as specified under 12 VAC 5-421-1700 by providing:
 - a. Except as specified under Subsection A 3 b of this section, an exposure time of at least 10 seconds for a chlorine solution specified under 12 VAC 5-421-1700 A,
 - b. An exposure time of at least 7 seconds for a chlorine solution of 50 mg/L that has a pH of 10 or less and a temperature of at least 100°F (38°C) or a pH of 8 or less and a temperature of at least 75°F (24°C),
 - c. An exposure time of at least 30 seconds for other chemical sanitizing solutions, or
 - d. An exposure time used in relationship with a combination of temperature, concentration, and pH that, when evaluated for efficacy, yields sanitization as defined in Subsection 12 VAC 5-421-10.
- B. Subsection A of this section does not apply to bed and breakfast facilities serving 18 or fewer customers.

Efficacious sanitization is dependent upon warewashing being conducted within certain parameters. Time is a parameter applicable to both chemical and hot water sanitization. The time that hot water or chemicals contact utensils or food-contact surfaces must be sufficient to destroy pathogens that may remain on surfaces after cleaning. Other parameters, such as

temperature or chemical concentration, are used in combination with time to deliver effective sanitization.

Part IV

Equipment, Utensils, and Linens

Article 8

Laundering

12 VAC 5-421-1910. Clean Linens.

4-801.11

Clean linens shall be free from food residues and other soiling matter.

Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness.

12 VAC 5-421-1920. Specifications.

4-802.11

- A. Linens that do not come in direct contact with food shall be laundered between operations if they become wet, sticky, or visibly soiled.
- B. Cloth gloves used as specified in 12 VAC 5-421-580 D shall be laundered before being used with a different type of raw animal food such as beef, lamb, pork, and fish.
- C. Linens and napkins that are used as specified under 12 VAC 5-421-560 and cloth napkins shall be laundered between each use.
 - D. Wet wiping cloths shall be laundered daily
- E. Dry wiping cloths shall be laundered as necessary to prevent contamination of food and clean serving utensils.

Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces. The laundering of wet wiping cloths before being used with a fresh solution of cleanser or sanitizer is designed to reduce the microbiological load in the cleanser and sanitizer and thereby reduce the possible transfer of microorganisms to food and nonfood-contact surfaces.

Soiled linens shall be kept in clean, nonabsorbent receptacles or clean, washable laundry bags and stored and transported to prevent contamination of food, clean equipment, clean utensils, and single-service and single-use articles.

Soiled linens may directly or indirectly contaminate food. Proper storage will reduce the possibility of contamination of food, equipment, utensils, and single-service and single-use articles.

12 VAC 5-421-1940. Mechanical Washing.

4-803.12

- A. Except as specified in Subsection B of this section, linens shall be mechanically washed.
- B. In food establishments in which only wiping cloths are laundered as specified in 12 VAC 5-421-1490 B, the wiping cloths may be laundered in a mechanical washer, sink designated only for laundering wiping cloths, or a warewashing or food preparation sink that is cleaned as specified under 12 VAC 5-421-1600.

Proper laundering of wiping cloths will significantly reduce the possibility that pathogenic microorganisms will be transferred to food, equipment, or utensils.

12 VAC 5-421-1950. Use of Laundry Facilities.

4-803.13

- A. Except as specified in Subsection B of this section, laundry facilities on the premises of a food establishment shall be used only for the washing and drying of items used in the operation of the establishment.
- B. Separate laundry facilities located on the premises for the purpose of general laundering such as for institutions providing boarding and lodging may also be used for laundering food establishment items.

Washing and drying items used in the operation of the establishment on the premises will help prevent the introduction of pathogenic microorganisms into the environment of the food establishment.

Part IV

Equipment, Utensils, and Linens

Article 9

Protection of Clean Items

12 VAC 5-421-1960. Equipment and Utensils, Air-Drying Required.

4-901.11

After cleaning and sanitizing, equipment and utensils:

- 1. Shall be air-dried or used after adequate draining as specified in Paragraph (a) of 21 CFR 178.1010 Sanitizing solutions, before contact with food; and
- 2. May not be cloth dried except that utensils that have been air-dried may be polished with cloths that are maintained clean and dry.

Items must be allowed to drain and to air-dry before being stacked or stored. Stacking wet items such as pans prevents them from drying and may allow an environment where microorganisms can begin to grow. Cloth drying of equipment and utensils is prohibited to prevent the possible transfer of microorganisms to equipment or utensils.

12 VAC 5-421-1970. Wiping Cloths, Air-Drying Locations.

4-901.12

Wiping cloths laundered in a food establishment that does not have a mechanical clothes dryer as specified in 12 VAC 5-421-1490 B shall be air-dried in a location and in a manner that prevents contamination of food, equipment, utensils, linens, and single-service and single-use articles and the wiping cloths. This section does not apply if wiping cloths are stored after laundering in a sanitizing solution as specified under 12 VAC 5-421-1700.

12 VAC 5-421-1980. Food-Contact Surfaces.

4-902.11

Lubricants shall be applied to food-contact surfaces that require lubrication in a manner that does not contaminate food-contact surfaces.

Food-contact surfaces must be lubricated in a manner that does not introduce contaminants to those surfaces.

12 VAC 5-421-1990. Equipment.

4-902.12

4-903.11

Equipment shall be reassembled so that food-contact surfaces are not contaminated.

Equipment must be reassembled in a way that food-contact surfaces are not contaminated.

12 VAC 5-421-2000. Equipment, Utensils, Linens, and Single-Service and Single-Use Articles.

- A. Except as specified in Subsection D of this section, cleaned equipment and utensils, laundered linens, and single-service and single-use articles shall be stored:
 - 1. In a clean, dry location;
 - 2. Where they are not exposed to splash, dust, or other contamination; and
 - 3. At least 6 inches (15 cm) above the floor.
- B. Clean equipment and utensils shall be stored as specified under Subsection A of this section and shall be stored:
 - 1. In a self-draining position that allows air drying; and
 - 2. Covered or inverted.
- C. Single-service and single-use articles shall be stored as specified under Subsection A of this section and shall be kept in the original protective package or stored by using other means that afford protection from contamination until used.
- D. Items that are kept in closed packages may be stored less than 6 inches (15 cm) above the floor on dollies, pallets, racks, and skids that are designed as provided under 12 VAC 5-421-1420.

Clean equipment and multiuse utensils which have been cleaned and sanitized, laundered linens, and single-service and single-use articles can become contaminated before their intended use in a variety of ways such as through water leakage, pest infestation, or other insanitary condition.

12 VAC 5-421-2010. Prohibitions.

4-903.12

- A. Except as specified in Subsection B of this section, cleaned and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may not be stored:
 - 1. In locker rooms;
 - 2. In toilet rooms or vestibules;
 - 3. In garbage rooms;
 - 4. In mechanical rooms;
 - 5. Under sewer lines that are not shielded to intercept potential drips;

- 6. Under leaking water lines including leaking automatic fire sprinkler heads or under lines on which water has condensed;
- 7. Under open stairwells; or
- 8. Under other sources of contamination.
- B. Laundered linens and single-service and single-use articles that are packaged or in a facility such as a cabinet may be stored in a locker room.

The improper storage of clean and sanitized equipment, utensils, laundered linens, and single-service and single-use articles may allow contamination before their intended use. Contamination can be caused by moisture from absorption, flooding, drippage, or splash. It can also be caused by food debris, toxic materials, litter, dust, and other materials. The contamination is often related to unhygienic employee practices, unacceptable high-risk storage locations, or improper construction of storage facilities.

12 VAC 5-421-2020. Kitchenware and Tableware.

4-904.11

- A. Single-service and single-use articles and cleaned and sanitized utensils shall be handled, displayed, and dispensed so that contamination of food- and lip-contact surfaces is prevented.
- B. Knives, forks, and spoons that are not prewrapped shall be presented so that only the handles are touched by employees and by consumers if consumer self-service is provided.
- C. Except as specified under Subsection B of this section, single-service articles that are intended for food- or lip-contact shall be furnished for consumer self-service with the original individual wrapper intact or from an approved dispenser.

12 VAC 5-421-2030. Soiled and Clean Tableware.

4-904.12

Soiled tableware shall be removed from consumer eating and drinking areas and handled so that clean tableware is not contaminated.

12 VAC 5-421-2040. Preset Tableware.

4-904.13

If Tableware is preset:

1. It shall be protected from contamination by being wrapped, covered, or inverted;

- 2. Exposed, unused settings shall be removed when a consumer is seated; or
- 3. Exposed, unused settings shall be cleaned and sanitized before further use if the settings are not removed when a consumer is seated.

Handling 12 VAC 5-421-2020 Kitchenware and Tableware. 12 VAC 5-421-2030 Soiled and Clean Tableware. 12 VAC 5-421-2040 Preset Tableware.

The presentation and/or setting of single-service and single-use articles and cleaned and sanitized utensils shall be done in a manner designed to prevent the contamination of food- and lip-contact surfaces.

Part V

Water, Plumbing, and Waste

Article 1

Water

12 VAC 5-421-2050. Approved System.*

5-101.11

Drinking water shall be obtained from an approved source that is:

- 1. A public water system; or
- 2. A nonpublic water system that is constructed, maintained, and operated according to law.

Water, unless it comes from a safe supply, may serve as a source of contamination for food, equipment, utensils, and hands. The major concern is that water may become a vehicle for transmission of disease organisms. Water can also become contaminated with natural or manmade chemicals. Therefore, for the protection of consumers and employees, water must be obtained from a source regulated by law and must be used, transported, and dispensed in a sanitary manner.

12 VAC 5-421-2060. System Flushing and Disinfection.*

5-101.12

A drinking water system shall be flushed and disinfected before being placed in service after construction, repair, or modification and after an emergency situation, such as a flood, that may introduce contaminants to the system.

During construction, repair, or modification, water systems may become contaminated with microbes from soil because pipes are installed underground or by chemicals resulting from soldering and welding. Floods and other incidents may also cause water to become contaminated. Chemical contaminants such as oils may also be present on or in the components of the system. To render the water safe, the system must be properly flushed and disinfected before being placed into service.

12 VAC 5-421-2070. Bottled Drinking Water.*

5-101.13

Bottled drinking water used or sold in a food establishment shall be obtained from approved sources in accordance with 21 CFR 129 - Processing and Bottling of Bottled drinking water.

Bottled water is obtained from a public water system or from a private source such as a spring or well. Either means of production must be controlled by public health law to protect the consumer from contaminated water.

12 VAC 5-421-2080. Quality Standards.*

5-102.11

Except as specified under 12 VAC 5-421-2090:

- A. Water from a public water system shall meet the applicable standards found in the Virginia Waterworks Regulations, 12 VAC 5-590; and
- B. Water from a nonpublic water system shall meet state drinking water quality standards.

Bacteriological and chemical standards have been developed for public drinking water supplies to protect public health. All drinking water supplies must meet standards required by law.

12 VAC 5-421-2090. Nondrinking Water.

5-102.12

- A. A nondrinking water supply shall be used only if its use is approved.
- B. Nondrinking water shall be used only for nonculinary purposes such as air conditioning, nonfood equipment cooling, fire protection, and irrigation.

Food establishments may use nondrinking water for purposes such as air-conditioning or fire protection. Nondrinking water is not monitored for bacteriological or chemical quality or safety as is drinking water. Consequently, certain safety precautions must be observed to prevent the contamination of food, drinking water, or food-contact surfaces. Identifying the piping designated as nondrinking waterlines and inspection for cross connections are examples of safety precautions.

12 VAC 5-421-2100. Sampling.

5-102.13

Except when used as specified under 12 VAC 5-421-2090, water from a nonpublic water system shall be sampled and tested at least annually and as required by state water quality regulations.

Wells and other types of individual water supplies may become contaminated through faulty equipment or environmental contamination of ground water. Periodic sampling is required by law to monitor the safety of the water and to detect any change in quality. The controlling agency must be able to ascertain that this sampling program is active and that the safety of the water is in conformance with the appropriate standards. Laboratory results are only as accurate as the sample submitted. Care must be taken not to contaminate samples. Proper sample collection and timely transportation to the laboratory are necessary to ensure the safety of drinking water used in the establishment.

12 VAC 5-421-2110. Sample Report.

5-102.14

The most recent sample report for the nonpublic water system shall be retained on file in the food establishment or the report shall be maintained as specified by state water quality regulations.

The most recent water sampling report must be kept on file to document a safe water supply.

12 VAC 5-421-2120. Capacity.*

5-103.11

- A. The water source and system shall be of sufficient capacity to meet the water demands of the food establishment.
- B. Hot water generation and distribution systems shall be sufficient to meet the peak hot water demands throughout the food establishment.

Availability of sufficient water is a basic requirement for proper sanitation within a food establishment. An insufficient supply of safe water will prevent the proper cleaning of items such as equipment and utensils and of food employees' hands.

Hot water required for washing items such as equipment and utensils and employees' hands, must be available in sufficient quantities to meet demand during peak water usage periods. Booster heaters for warewashers that use hot water for sanitizing are designed to raise the temperature of hot water to a level that ensures sanitization. If the volume of water reaching the booster heater is not sufficient or hot enough, the required temperature for sanitization can not be reached. Manual washing of food equipment and utensils is most effective when hot water is used. Unless utensils are clean to sight and touch, they cannot be effectively sanitized.

12 VAC 5-421-2130. Pressure.

5-103.12

Water under pressure shall be provided to all fixtures, equipment, and nonfood equipment that are required to use water except that water supplied as specified under 12 VAC 5-421-2160 1 and 2 to a temporary food establishment or in response to a temporary interruption of a water supply need not be under pressure.

Inadequate water pressure could lead to situations that place the public health at risk. For example, inadequate pressure could result in improper handwashing or equipment operation. Sufficient water pressure ensures that equipment such as mechanical warewashers operate according to manufacturer's specifications.

12 VAC 5-421-2140. Reserved.

5-103.11

12 VAC 5-421-2150. Distribution, Delivery, and Retention System.

5-104.11

Water shall be received from the source through the use of:

- 1. An approved public water main; or
- 2. One or more of the following that shall be constructed, maintained, and operated according to law:
 - a. Nonpublic water main, water pumps, pipes, hoses, connections, and other appurtenances,
 - b. Water transport vehicles, and
 - c. Water containers.

Inadequate water systems may serve as vehicles for contamination of food or food-contact surfaces. This requirement is intended to ensure that sufficient volumes of water are provided from supplies shown to be safe, through a distribution system which is protected.

12 VAC 5-421-2160. Alternative Water Supply.

5-104.12

Water meeting the requirements specified under 12 VAC 5-421-2050 through 12 VAC 5-421-2130 shall be made available for a mobile facility, for a temporary food establishment without a permanent water supply, and for a food establishment with a temporary interruption of its water supply through:

- 1. A supply of containers of commercially bottled drinking water;
- 2. One or more closed portable water containers;
- 3. An enclosed vehicular water tank;
- 4. An on-premises water storage tank; or
- 5. Piping, tubing, or hoses connected to an adjacent approved source.

Water from an approved source can be contaminated if inappropriately conveyed. Improperly constructed and maintained water mains, pumps, hoses, connections, and other appurtenances, as well as transport vehicles and containers, may result in contamination of safe water and render it hazardous to human health.

Part V

Water, Plumbing, and Waste

Article 2

Plumbing System

12 VAC 5-421-2170. Approved Materials.*

5-201.11

- A. A plumbing system and hoses conveying water shall be constructed and repaired with approved materials according to law.
 - B. A water filter shall be made of safe materials.

Plumbing systems and hoses conveying water must be made of approved materials and be smooth, durable, nonabsorbent, and corrosion-resistant. If not, the system may constitute a health hazard because unsuitable surfaces may harbor disease organisms or it may be constructed of materials that may, themselves, contaminate the water supply.

12 VAC 5-421-2180. Approved System and Cleanable Fixtures.*

5-202.11

- A. A plumbing system shall be designed, constructed, and installed according to law.
- B. A plumbing fixture such as a handwashing lavatory, toilet, or urinal shall be easily cleanable.^N

Water within a system will leach minute quantities of materials out of the components of the system. To make sure none of the leached matter is toxic or in a form that may produce detrimental effects, even through long-term use, all materials and components used in water systems must be of an approved type. New or replacement items must be tested and approved based on current standards.

Improperly designed, installed, or repaired water systems can have inherent deficiencies such as improper access openings, dead spaces, and areas difficult or impossible to clean and disinfect. Dead spaces allow water quality to degrade since they are out of the constant circulation of the system. Fixtures such as warewashing sinks that are not easily cleanable may lead to the contamination of food products.

12 VAC 5-421-2190. Handwashing Lavatory, Water Temperature, and Flow. **5-202.12**

- A. A handwashing lavatory shall be equipped to provide water at a temperature of at least 110°F (43°C) through a mixing valve or combination faucet.
 - B. A steam mixing valve may not be used at a handwashing lavatory.
- C. A self-closing, slow-closing, or metering faucet shall provide a flow of water for at least 15 seconds without the need to reactivate the faucet.

Warm water is more effective than cold water in removing the fatty soils encountered in kitchens. An adequate flow of warm water will cause soap to lather and aid in flushing soil quickly from the hands. An inadequate flow or temperature of water may lead to poor handwashing practices by food employees. A mixing valve or combination faucet is needed to provide properly tempered water for handwashing. Steam mixing valves are not allowed for this use because they are hard to control and injury by scalding is a possible hazard.

An air gap between the water supply inlet and the flood level rim of the plumbing fixture, equipment, or nonfood equipment shall be at least twice the diameter of the water supply inlet and may not be less than 1 inch (25 mm).

During periods of extraordinary demand, drinking water systems may develop negative pressure in portions of the system. If a connection exists between the system and a source of contaminated water during times of negative pressure, contaminated water may be drawn into and foul the entire system. Standing water in sinks, dipper wells, steam kettles, and other equipment may become contaminated with cleaning chemicals or food residue. To prevent the introduction of this liquid into the water supply through back siphonage, various means may be used.

The water outlet of a drinking water system must not be installed so that it contacts water in sinks, equipment, or other fixtures that use water. Providing an air gap between the water supply outlet and the flood level rim of a plumbing fixture or equipment prevents contamination that may be caused by backflow.

12 VAC 5-421-2210. Backflow Prevention Device, Design Standard.

5-202.14

A backflow or backsiphonage prevention device installed on a water supply system shall comply with the Virginia Uniform Statewide Building Code (13 VAC 5-61-10 et seq.) for construction, installation, maintenance, inspection, and testing for that specific application and type of device.

In some instances an air gap is not practical such as is the case on the lower rinse arm for the final rinse of warewashers. This arm may become submerged if the machine drain becomes clogged. If this failure occurs, the machine tank would fill to the flood level rim, which is above the rinse arm. A backflow prevention device is used to avoid potential backflow of contaminated water when an air gap is not practical. The device provides a break to the atmosphere in the event of a negative pressure within the system.

Minerals contained in water and solid particulate matter carried in water may coat moving parts of the device or become lodged between them over time. This may render the device inoperative. To minimize such an occurrence, only devices meeting certain standards of construction, installation, maintenance, inspection, and testing for that application may be used. The necessary maintenance can be facilitated by installing these devices in accessible locations.

A water filter, screen, and other water conditioning device installed on water lines shall be designed to facilitate disassembly for periodic servicing and cleaning. A water filter element shall be of the replaceable type.

Water conditioning devices must be designed for easy disassembly for servicing so that they can be maintained in a condition that allows them to perform the function for which they were designed.

12 VAC 5-421-2230. Handwashing Lavatory.*

5-203.11

A. Except as specified in Subsection B of this section, at least 1 handwashing lavatory, or the number of handwashing lavatories necessary for their convenient use by employees in areas specified under 12 VAC 5-421-2280, and not fewer than the number of handwashing lavatories required by law shall be provided.

B. If approved, when food exposure is limited and handwashing lavatories are not conveniently available, such as in some mobile or temporary food establishments or at some vending machine locations, employees may use chemically treated towelettes for handwashing.

Because handwashing is such an important factor in the prevention of foodborne illness, sufficient facilities must be available to make handwashing not only possible, but likely.

12 VAC 5-421-2240. Toilets and Urinals.*

5-203.12

At least 1 toilet and not fewer than the toilets required by law shall be provided. If authorized by law and urinals are substituted for toilets, the substitution shall be done as specified in law.

Adequate, sanitary toilet facilities are necessary for the proper disposal of human waste, which carries pathogenic microorganisms, and for preventing the spread of disease by flies and other insects.

Toilet facilities must be of sanitary design and kept clean and in good repair to prevent food contamination and to motivate employees to use sanitary practices in the establishment.

12 VAC 5-421-2250. Service Sink.

5-202.13

At least 1 service sink or 1 curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and for the disposal of mop water and similar liquid waste.

Mop water and similar liquid wastes are contaminated with microorganisms and other filth. Waste water must be disposed of in a sanitary manner that will not contaminate food or food equipment. A service sink or curbed cleaning facility with a drain allows for such disposal.

12 VAC 5-421-2260. Backflow Prevention Device, When Required.* 5-203.14

A plumbing system shall be installed to preclude backflow of a solid, liquid, or gas contaminant into the water supply system at each point of use at the food establishment, including on a hose bibb (threaded faucet) if a hose is attached or on a hose bibb if a hose is not attached and backflow prevention is required by law, by:

- 1. Providing an air gap as specified under 12 VAC 5-421-2200; or
- 2. Installing an approved backflow prevention device as specified under 12 VAC 5-421-2210.

The delivery end of hoses attached to hose bibbs on a drinking water line may be dropped into containers filled with contaminated water or left in puddles on the floor or in other possible sources of contamination. A backflow prevention device must be installed on the hose bibb to prevent the back siphonage of contaminated liquid into the drinking water system during occasional periods of negative pressure in the water line.

12 VAC 5-421-2270. Backflow Prevention Device, Carbonator.

5-203.15

Reserved.

12 VAC 5-421-2280. Handwashing Lavatory.*

5-204.11

A handwashing lavatory shall be located:

- 1. To be readily accessible for use by employees in food preparation, food dispensing, and warewashing areas; and
- 2. In, or immediately adjacent to, toilet rooms.

Hands are probably the most common vehicle for the transmission of pathogens to foods in an establishment. Hands can become soiled with a variety of contaminants during routine operations. Some employees are unlikely to wash their hands unless properly equipped handwashing facilities are accessible in the immediate work area. Facilities which are improperly located may be blocked by portable equipment or stacked full of soiled utensils and other items, rendering the facility unavailable for regular employee use. Nothing must block the approach to a handwashing facility thereby discouraging its use, and the facility must be kept clean and well stocked with soap and sanitary towels to encourage frequent use.

12 VAC 5-421-2290. Backflow Prevention Device, Location.

5-204.12

A backflow prevention device shall be located so that it may be serviced and maintained.

Backflow prevention devices are meant to protect the drinking water system from contamination caused by backflow. If improperly placed, backflow prevention devices will not work. If inconveniently located, these devices may not be accessed when systems are extended, altered, serviced, or replaced. Over a period of time, unserviced devices may fail and system contamination may occur.

12 VAC 5-421-2300. Conditioning Device, Location.

5-204.13

A water filter, screen, and other water conditioning device installed on water lines shall be located to facilitate disassembly for periodic servicing and cleaning.

When not located for easy maintenance, conditioning devices will be inconvenient to access and devices such as filters, screens, and water softeners will become clogged because they are not properly serviced.

12 VAC 5-421-2310. Using a Handwashing Lavatory.

5-205.11

- A. A handwashing lavatory shall be maintained so that it is accessible at all times for employee use.
- B. A handwashing lavatory may not be used for purposes other than handwashing.

Facilities must be maintained in a condition that promotes handwashing and restricted for that use. Convenient accessibility of a handwashing facility encourages timely handwashing which provides a break in the chain of contamination from the hands of food employees to food or food-contact surfaces. Sinks used for food preparation and warewashing can become sources of contamination if used as handwashing facilities by employees returning from the toilet or from duties which have contaminated their hands.

12 VAC 5-421-2320. Prohibiting a Cross Connection.*

5-205.12

- A. Except as specified in 9 CFR 308.3(d) for firefighting, a person may not create a cross connection by connecting a pipe or conduit between the drinking water system and a nondrinking water system or a water system of unknown quality.
- B. The piping of a nondrinking water system shall be durably identified so that it is readily distinguishable from piping that carries drinking water.^N

Nondrinking water may be of unknown or questionable origin. Waste water is either known or suspected to be contaminated. Neither of these sources can be allowed to contact and contaminate the drinking water system.

12 VAC 5-421-2330. Scheduling Inspection and Service for a Water System Device. **5-205.13**

A device such as a water treatment device or backflow preventer shall be scheduled for inspection and service, in accordance with manufacturer's instructions and as necessary to prevent device failure based on local water conditions, and records demonstrating inspection and service shall be maintained by the person in charge.

Water system devices, such as filters and backflow preventers, are affected by the water in the system. How devices are affected depends on water quality, especially pH, hardness, and suspended particulate matter in the water. Complexity of the device is also a factor. Manufacturer recommendations, as well as inspection and maintenance schedules for these devices, must be strictly followed to prevent failure during operation.

12 VAC 5-421-2340. Water Reservoir of Fogging Devices, Cleaning.* 5-205.14

- A. A reservoir that is used to supply water to a device such as a produce fogger shall be:
 - 1. Maintained in accordance with manufacturer's specifications; and
 - 2. Cleaned in accordance with manufacturer's specifications or according to the procedures specified under Subsection B of this section, whichever is more stringent.
- B. Cleaning procedures shall include at least the following steps and shall be conducted at least once a week:
 - 1 Draining and complete disassembly of the water and aerosol contact parts;

- 2 Brush-cleaning the reservoir, aerosol tubing, and discharge nozzles with a suitable detergent solution;
- 3. Flushing the complete system with water to remove the detergent solution and particulate accumulation; and
- 4. Rinsing by immersing, spraying, or swabbing the reservoir, aerosol tubing, and discharge nozzles with at least 50 mg/L (ppm) hypochlorite solution.

Water reservoirs that have poor water exchange rates, such as reservoirs for some humidifiers or aerosol or fogging devices, and that are directly or indirectly open to the atmosphere, may be contaminated with respiratory pathogens such as **Legionella pneumophila**. This organism is extremely infectious and can be transmitted through very small droplets of a fogger or humidifier. It is important that the manufacturer's cleaning and maintenance schedule be scrupulously followed to prevent a reservoir from colonization by this bacterium.

12 VAC 5-421-2350. System Maintained in Good Repair.*

5-205.15

A plumbing system shall be:

- 1. Repaired according to law; and
- 2. Maintained in good repair.^S

Improper repair or maintenance of any portion of the plumbing system may result in potential health hazards such as cross connections, backflow, or leakage. These conditions may result in the contamination of food, equipment, utensils, linens, or single-service or single-use articles. Improper repair or maintenance may result in the creation of obnoxious odors or nuisances, and may also adversely affect the operation of warewashing equipment or other equipment which depends on sufficient volume and pressure to perform its intended functions.

Part V

Water, Plumbing and Waste

Article 3

Mobile Water Tank and Mobile Food Establishment Water Tank

12 VAC 5-421-2360. Approved Materials.

5-301.11

Materials that are used in the construction of a mobile water tank, mobile food establishment water tank, and appurtenances shall be:

- 1. Safe;
- 2. Durable, corrosion-resistant, and nonabsorbent; and
- 3. Finished to have a smooth, easily cleanable surface.

Materials used in the construction of a mobile water tank are affected by the water they contact. Tank liners may deteriorate and flake. Metals or platings can be toxic. To prevent the degradation of the quality of the water, it is important that the materials used in the construction of the tank are suitable for such use.

12 VAC 5-421-2370. Enclosed System, Sloped to Drain.

5-302.11

A mobile water tank shall be:

- 1. Enclosed from the filling inlet to the discharge outlet; and
- 2. Sloped to an outlet that allows complete drainage of the tank.

12 VAC 5-421-2380. Inspection and Cleaning Port, Protected and Secured.

5-302.12

If a water tank is designed with an access port for inspection and cleaning, the opening shall be in the top of the tank and:

- 1. Flanged upward at least one-half inch (13 mm); and
- 2. Equipped with a port cover assembly that is:
 - a. Provided with a gasket and a device for securing the cover in place, and
 - b. Flanged to overlap the opening and sloped to drain.

Design and 12 VAC 5-421-2370 Enclosed System, Sloped to Drain.

Construction 12 VAC 5-421-2380 Inspection and Cleaning Port, Protected and Secured.

The tank must be a closed system from the filling inlet to the outlet to prevent contamination of water. It is important that the bottom of the tank be sloped to the outlet to allow the tank to drain completely, to facilitate the proper cleaning and disinfection of the tank, and to prevent the retention of water or solutions after cleaning.

Some tanks are designed with an access opening to facilitate the cleaning and servicing of the water tank. The access must be constructed to prevent the opening from becoming a source of contamination of the water.

12 VAC 5-421-2390. "V" Type Threads, Use Limitation.

5-302.13

A fitting with "V" type threads on a water tank inlet or outlet shall be allowed only when a hose is permanently attached.

V-type threads are difficult to clean if contaminated with food or waste. To prevent the contamination of the drinking water, this type of thread should only be used on water tank inlets and outlets if the connection is permanent which eliminates exposed, difficult-to-clean threads.

12 VAC 5-421-2400. Tank Vent, Protected.

5-302.14

If provided, a water tank vent shall terminate in a downward direction and shall be covered with:

- 1. 16 mesh to 1 inch (16 mesh to 25.4 mm) screen or equivalent when the vent is in a protected area; or
- 2. A protective filter when the vent is in an area that is not protected from windblown dirt and debris.

Water tanks are equipped with a vent to preclude distortion during filling or draining. The vent should be equipped with a suitable screen or filter to protect the tank against the entry of insects or other vermin that may contaminate the water supply.

12 VAC 5-421-2410. Inlet and Outlet, Sloped to Drain.

5-302.15

A. A water tank and its inlet and outlet shall be sloped to drain.

B. A water tank inlet shall be positioned so that it is protected from contaminants such as waste discharge, road dust, oil, or grease.

Both the inlet and outlet must be sloped to drain to prevent the pooling of possibly contaminated water or sanitizing solution.

12 VAC 5-421-2420. Hose, Construction and Identification.

5-302.16

A hose used for conveying drinking water from a water tank shall be:

- 1. Safe;
- 2. Durable, corrosion-resistant, and nonabsorbent;
- 3. Resistant to pitting, chipping, crazing, scratching, scoring, distortion, and decomposition;
- 4. Finished with a smooth interior surface; and
- 5. Clearly and durably identified as to its use if not permanently attached.

Hoses used to fill potable water tanks should be dedicated for that one task and should be identified for that use only to prevent contaminating the water. Hoses must be made of a material that will not leach detrimental substances into the water.

12 VAC 5-421-2430. Filter, Compressed Air.

5-303.11

A filter that does not pass oil or oil vapors shall be installed in the air supply line between the compressor and drinking water system when compressed air is used to pressurize the water tank system.

Compressor pistons are lubricated with oil to minimize wear. Some of the oil is carried into the air lines and if not intercepted may contaminate the tank and water lines.

12 VAC 5-421-2440. Protective Cover or Device.

5-303.12

A cap and keeper chain, closed cabinet, closed storage tube, or other approved protective cover or device shall be provided for a water inlet, outlet, and hose.

Protective equipment provided for openings of the water supply must be in use to prevent contamination which may be present where the supply is exposed to the environment, i.e., at water inlets or outlets or the ends of transfer hoses.

12 VAC 5-421-2450. Mobile Food Establishment Tank Inlet.

5-303.13

A mobile food establishment's water tank inlet shall be:

- 1. Three-fourths inch (19.1 mm) in inner diameter or less; and
- 2. Provided with a hose connection of a size or type that will prevent its use for any other service.

Mobile units may be particularly vulnerable to environmental contamination if soiled hose connections are coupled to the tank inlet.

12 VAC 5-421-2460. System Flushing and Disinfection.*

5-304.11

A water tank, pump, and hoses shall be flushed and sanitized before being placed in service after construction, repair, modification, and periods of nonuse.

Contaminants of various types may be introduced into a water system during construction or repair or other incidents. The system must be flushed and sanitized after maintenance and before it is placed into service to prevent contamination of the water introduced into the tank.

12 VAC 5-421-2470. Using a Pump and Hoses, Backflow Prevention. 5-304.12

A person shall operate a water tank, pump, and hoses so that backflow and other contamination of the water supply are prevented.

When a water system includes a pump, or a pump is used in filling a water tank, care must be taken during hookup to prevent negative pressure on the supplying water system.

Backflow prevention to protect the water supply is especially necessary during cleaning and sanitizing operations on a mobile system.

12 VAC 5-421-2480. Protecting Inlet, Outlet, and Hose Fitting.

5-304.13

If not in use, a water tank and hose inlet and outlet fitting shall be protected using a cover or device as specified under 12 VAC 5-421-2440.

When not connected for use, water inlets, outlets, and hose fittings should be closed to the environment. Unless capped or otherwise protected, filling inlets, outlets, and hoses may become contaminated by dust or vermin.

12 VAC 5-421-2490. Tank, Pump, and Hoses, Dedication.

5-304.14

- A. Except as specified in Subsection B of this section, a water tank, pump, and hoses used for conveying drinking water shall be used for no other purpose.
- B. Water tanks, pumps, and hoses approved for liquid foods may be used for conveying drinking water if they are cleaned and sanitized before they are used to convey water.

Hoses, pumps, and tanks used for food or water may not be used for other liquids because this may contaminate the water supply. If a hose, tank, or pump has been used to transfer liquid food, the equipment must be cleaned and sanitized before using it for water delivery. Failure to properly clean and sanitize the equipment would introduce nutrients, and possibly bacteria, into the water as well as inactivate residual chlorine from public water supplies.

Part V

Water, Plumbing, and Waste

Article 4

Sewage, Other Liquid Waste, and Rainwater

12 VAC 5-421-2500. Mobile Holding Tank Capacity and Drainage.

5-401.11

A sewage holding tank in a mobile food establishment shall be:

- 1. Sized 15 percent larger in capacity than the water supply tank; and
- 2. Sloped to a drain that is 1 inch (25 mm) in inner diameter or greater, equipped with a shut-off valve.

Liquid waste from a mobile or temporary food establishment must be stored in a properly constructed waste tank to discourage the attraction of flies and other vermin. The waste tank must be 15% larger than the water storage tank to allow for storage of wastes and used water from the drinking water supply tank. The drain from the waste tank must be larger than the filling hose to prevent the use of the drinking water filling hose to drain the waste tank.

12 VAC 5-421-2510. Establishment Drainage System.

5-402.10

Food establishment drainage systems, including grease traps, that convey sewage shall be designed and installed as specified under 12 VAC 5-421-2180 A.

The drainage system must be designed and installed properly to prevent the backup of sewage and the possible contamination of foods or food-contact surfaces in the establishment.

12 VAC 5-421-2520. Backflow Prevention.*

5-402.11

- A. Except as specified in Subsection B and C of this section, a direct connection may not exist between the sewage system and a drain originating from equipment in which food, portable equipment, or utensils are placed.
- B. If allowed by law, a warewashing machine may have a direct connection between its waste outlet and a floor drain when the machine is located within 5 feet (1.5 m) of a trapped floor drain and the machine outlet is connected to the inlet side of a properly vented floor drain trap.
 - C. If allowed by law, a warewashing or culinary sink may have a direct connection.

Improper plumbing installation or maintenance may result in potential health hazards such as cross connections, back siphonage or backflow. These conditions may result in the contamination of food, utensils, equipment, or other food-contact surfaces. It may also adversely affect the operation of equipment such as warewashing machines.

12 VAC 5-421-2530. Grease Trap.

5-402.12

If used, a grease trap shall be located to be easily accessible for cleaning.

Failure to locate a grease trap so that it can be properly maintained and cleaned could result in the harborage of vermin and/or the failure of the sewage system.

12 VAC 5-421-2540. Conveying Sewage.*

5-402.13

Sewage shall be conveyed to the point of disposal through an approved sanitary sewage system or other system, including use of sewage transport vehicles, waste retention tanks, pumps, pipes, hoses, and connections that are constructed, maintained, and operated according to law.

12 VAC 5-421-2550. Removing Mobile Food Establishment Wastes.

5-402.14

Sewage and other liquid wastes shall be removed from a mobile food establishment at an approved waste servicing area or by a sewage transport vehicle in such a way that a public health hazard or nuisance is not created.

12 VAC 5-421-2540 Conveying Sewage.*
12 VAC 5-421-2550 Removing Mobile Food Establishment
Waste.

Improper disposal of waste provides a potential for contamination of food, utensils, and equipment and, therefore, may cause serious illness or disease outbreaks. Proper removal is required to prevent contamination of ground surfaces and water supplies, or creation of other insanitary conditions that may attract insects and other vermin.

12 VAC 5-421-2560. Flushing a Waste Retention Tank.

5-402.15

A tank for liquid waste retention shall be thoroughly flushed and drained in a sanitary manner during the servicing operation.

Thoroughly flushing the liquid waste retention tank will prevent the buildup of deposits within the tank which could affect the proper operation of the tank.

12 VAC 5-421-2570. Approved Sewage Disposal System.*

5-403.11

Sewage shall be disposed through an approved facility that is:

- 1. A public sewage treatment plant; or
- 2. An individual sewage disposal system that is sized, constructed, maintained, and operated according to law.

Many diseases can be transmitted from one person to another through fecal contamination of food and water. This transmission can be indirect. Proper disposal of human wastes greatly reduces the risk of fecal contamination. This Code provision is intended to ensure that wastes will not contaminate ground surfaces or water supplies; pollute surface waters; be accessible to children or pets; or allow rodents or insects to serve as vectors of disease from this source.

12 VAC 5-421-2580. Other Liquid Wastes and Rainwater.

5-403.12

Condensate drainage and other nonsewage liquids and rainwater shall be drained from point of discharge to disposal according to law.

Liquid food wastes and rainwater can provide a source of bacterial contamination and support populations of pests. Proper storage and disposal of wastes and drainage of rainwater eliminate these conditions.

Part V

Water, Plumbing, and Waste

Article 5

Refuse, Recyclables, and Returnables

12 VAC 5-421-2590. Indoor Storage Area.

5-501.10

If located within the food establishment, a storage area for refuse, recyclables, and returnables shall meet the requirements specified under 12 VAC 5-421-2790, 12 VAC 5-421-2810 through 12 VAC 5-421-2880, 12 VAC 5-421-2930, and 12 VAC 5-421-2940.

12 VAC 5-421-2600. Outdoor Storage Surface.

5-501.10

An outdoor storage surface for refuse, recyclables, and returnables shall be constructed of nonabsorbent material such as concrete or asphalt and shall be smooth, durable, and sloped to drain.

12 VAC 5-421-2610. Outdoor Enclosure.

5-501.12

If used, an outdoor enclosure for refuse, recyclables, and returnables shall be constructed of durable and cleanable materials.

12 VAC 5-421-2620. Receptacles.

5-501.13

A. Except as specified in Subsection B of this section, receptacles and waste handling units for refuse, recyclables, and returnables and for use with materials containing food residue shall be durable, cleanable, insect- and rodent-resistant, leakproof, and nonabsorbent.

B. Plastic bags and wet strength paper bags may be used to line receptacles for storage inside the food establishment, or within closed outside receptacles.

12 VAC 5-421-2630. Receptacles in Vending Machines.

5-501.14

A refuse receptacle may not be located within a vending machine, except that a receptacle for beverage bottle crown closures may be located within a vending machine.

12 VAC 5-421-2640. Outside Receptacles.

5-501.15

- A. Receptacles and waste handling units for refuse, recyclables, and returnables used with materials containing food residue and used outside the food establishment shall be designed and constructed to have tight-fitting lids, doors, or covers.
- B. Receptacles and waste handling units for refuse and recyclables such as an on-site compactor shall be installed so that accumulation of debris and insect and rodent attraction and harborage are minimized and effective cleaning is facilitated around and, if the unit is not installed flush with the base pad, under the unit.

12 VAC 5-421-2650. Storage Areas, Rooms, and Receptacles, Capacity and Availability.

5-501.16

- A. An inside storage room and area and outside storage area and enclosure, and receptacles shall be of sufficient capacity to hold refuse, recyclables, and returnables that accumulate.
- B. A receptacle shall be provided in each area of the food establishment or premises where refuse is generated or commonly discarded, or where recyclables or returnables are placed.
- C. If disposable towels are used at handwashing lavatories, a waste receptacle shall be located at each lavatory or group of adjacent lavatories.

12 VAC 5-421-2660. Toilet Room Receptacle, Covered.

5-501.17

A toilet room used by females shall be provided with a covered receptacle for sanitary napkins.

12 VAC 5-421-2670. Cleaning Implements and Supplies.

5-501.18

A. Except as specified in Subsection B of this section, suitable cleaning implements and supplies such as high pressure pumps, hot water, steam, and detergent shall be provided as necessary for effective cleaning of receptacles and waste handling units for refuse, recyclables, and returnables.

B. If approved, off-premises-based cleaning services may be used if on-premises cleaning implements and supplies are not provided.

12 VAC 5-421-2680. Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location. **5-501.19**

- A. An area designated for refuse, recyclables, returnables, and, except as specified in Subsection B of this section, a redeeming machine for recyclables or returnables shall be located so that it is separate from food, equipment, utensils, linens, and single-service and single-use articles and a public health hazard or nuisance is not created.
- B. A redeeming machine may be located in the packaged food storage area or consumer area of a food establishment if food, equipment, utensils, linens, and single-service and single-use articles are not subject to contamination from the machines and a public health hazard or nuisance is not created.
- C. The location of receptacles and waste handling units for refuse, recyclables, and returnables may not create a public health hazard or nuisance or interfere with the cleaning of adjacent space.

12 VAC 5-421-2690. Storing Refuse, Recyclables, and Returnables.

5-501.110

Refuse, recyclables, and returnables shall be stored in receptacles or waste handling units so that they are inaccessible to insects and rodents.

12 VAC 5-421-2700. Areas, Enclosures, and Receptacles, Good Repair.

5-501.111

Storage areas, enclosures, and receptacles for refuse, recyclables, and returnables shall be maintained in good repair.

12 VAC 5-421-2710. Outside Storage Prohibitions.

5-501.112

A. Except as specified in Subsection B of this section, refuse receptacles not meeting the requirements specified under 12 VAC 5-421-2620 A such as receptacles that are not rodent-resistant, unprotected plastic bags and paper bags, or baled units that contain materials with food residue may not be stored outside.

B. Cardboard or other packaging material that does not contain food residues and that is awaiting regularly scheduled delivery to a recycling or disposal site may be stored outside without being in a covered receptacle if it is stored so that it does not create a rodent harborage problem.

12 VAC 5-421-2720. Covering Receptacles.

5-501.113

Receptacles and waste handling units for refuse, recyclables, and returnables shall be kept covered:

- 1. Inside the food establishment if the receptacles and units:
 - a. Contain food residue and are not in continuous use; or
 - b. After they are filled; and
- 2. With tight-fitting lids or doors if kept outside the food establishment.

12 VAC 5-421-2730. Using Drain Plugs.

5-501.114

Drains in receptacles and waste handling units for refuse, recyclables, and returnables shall have drain plugs in place.

12 VAC 5-421-2740. Maintaining Refuse Areas and Enclosures.

5-501.115

A storage area and enclosure for refuse, recyclables, or returnables shall be maintained free of unnecessary items, as specified under 12 VAC 5-421-3300, and clean.

12 VAC 5-421-2750. Cleaning Receptacles.

5-501.116

- A. Receptacles and waste handling units for refuse, recyclables, and returnables shall be thoroughly cleaned in a way that does not contaminate food, equipment, utensils, linens, or single-service and single-use articles, and waste water shall be disposed of as specified under 12 VAC 5-421-2550.
- B. Soiled receptacles and waste handling units for refuse, recyclables, and returnables shall be cleaned at a frequency necessary to prevent them from developing a buildup of soil or becoming attractants for insects and rodents.

Facilities	12 VAC 5-421-2590	Indoor Storage Area.
on	12 VAC 5-421-2600	Outdoor Storage Surface.
the Premises	12 VAC 5-421-2610	Outdoor Enclosure.
	12 VAC 5-421-2620	Receptacles.
	12 VAC 5-421-2630	Receptacles in Vending Machines.
	12 VAC 5-421-2640	Outside Receptacles.
	12 VAC 5-421-2650	Storage Areas, Rooms, and Receptacles, Capacity and Availability.
	12 VAC 5-421-2660	Toilet Room Receptacle, Covered.
	12 VAC 5-421-2670	Cleaning Implements and Supplies.
	12 VAC 5-421-2680	Storage Areas, Redeeming Machines, Receptacles and Waste Handling Units, Location.
	12 VAC 5-421-2690	Storage Refuse, Recyclables, and Returnables
	12 VAC-5-420-2700	Areas, Enclosures, and Receptacles, Good Repair.
	12 VAC 5-421-2710	Outside Storage Prohibitions.
	12 VAC 5-421-2720	Covering Receptacles.
	12 VAC 5-421-2730	Using Drain Plugs.
	12 VAC 5-421-2740	Maintaining Refuse Areas and Enclosures.
	12 VAC 5-421-2750	Cleaning Receptacles.

Proper storage and disposal of garbage and refuse are necessary to minimize the development of odors, prevent such waste from becoming an attractant and harborage or breeding place for insects and rodents, and prevent the soiling of food preparation and food service areas. Improperly handled garbage creates nuisance conditions, makes housekeeping difficult, and may be a possible source of contamination of food, equipment, and utensils.

Storage areas for garbage and refuse containers must be constructed so that they can be thoroughly cleaned in order to avoid creating an attractant or harborage for insects or rodents. In addition, such storage areas must be large enough to accommodate all the containers necessitated by the operation in order to prevent scattering of the garbage and refuse.

All containers must be maintained in good repair and cleaned as necessary in order to store garbage and refuse under sanitary conditions as well as to prevent the breeding of flies. Garbage containers should be available wherever garbage is generated to aid in the proper disposal of refuse.

Outside receptacles must be constructed with tight-fitting lids or covers to prevent the scattering of the garbage or refuse by birds, the breeding of flies, or the entry of rodents.

Proper equipment and supplies must be made available to accomplish thorough and proper cleaning of garbage storage areas and receptacles so that unsanitary conditions can be eliminated.

12 VAC 5-421-2760. Removal Frequency.

5-502.11

Refuse, recyclables, and returnables shall be removed from the premises at a frequency that will minimize the development of objectionable odors and other conditions that attract or harbor insects and rodents.

12 VAC 5-421-2770. Receptacles or Vehicles.

5-502.12

Refuse, recyclables, and returnables shall be removed from the premises by way of:

- 1. Portable receptacles that are constructed and maintained according to law; or
- 2. A transport vehicle that is constructed, maintained, and operated according to law.

Removal 12 VAC 5-421-2760 Frequency.

12 VAC 5-421-2770 Receptacles or Vehicles.

Refuse, recyclables, and returnable items, such as beverage cans and bottles, usually contain a residue of the original contents. Spillage from these containers soils receptacles and storage areas and becomes an attractant for insects, rodents, and other pests. The handling of these materials entails some of the same problems and solutions as the handling of garbage and refuse. Problems are minimized when all of these materials are removed from the premises at a reasonable frequency.

12 VAC 5-421-2780. Community or Individual Facility.

5-503.11

Solid waste not disposed of through the sewage system such as through grinders and pulpers shall be recycled or disposed of in an approved public or private community recycling or refuse facility; or solid waste shall be disposed of in an individual refuse facility such as a landfill or incinerator which is sized, constructed, maintained, and operated according to law.

Alternative means of solid waste disposal must be conducted properly to prevent environmental consequences and the attraction of insects, rodents, and other pests.

Part VI

Physical Facilities

Article 1

Materials for Construction and Repair

12 VAC 5-421-2790. Indoor Areas - Surface Characteristics.

6-101.11

- A. Except as specified in Subsection B of this section, materials for indoor floor, wall, and ceiling surfaces under conditions of normal use shall be:
 - 1. Smooth, durable, and easily cleanable for areas where food establishment operations are conducted:
 - 2. Closely woven and easily cleanable carpet for carpeted areas; and
 - 3. Nonabsorbent for areas subject to moisture such as food preparation areas, walk-in refrigerators, warewashing areas, toilet rooms, mobile food establishment servicing areas, and areas subject to flushing or spray cleaning methods.
 - B. In a temporary food establishment:
 - 1. A floor may be concrete, if graded to drain, machine-laid asphalt, or dirt or gravel if it is covered with mats, removable platforms, duckboards, or other suitable approved materials that are effectively treated to control dust and mud; and
 - 2. Walls and ceilings may be constructed of a material that protects the interior from the weather and windblown dust and debris.
- C. In lieu of subsection A of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

Floors, walls, and ceilings that are constructed of smooth and durable surface materials are more easily cleaned.

Floor surfaces that are graded to drain and consist of effectively treated materials will prevent contamination of foods from dust and organisms from pooled moisture.

The special requirements for carpeting materials and nonabsorbent materials in areas subject to moisture are intended to ensure that the cleanability of these surfaces is retained.

Although food served from temporary food establishments is subject to the same potential for contamination as food served in permanent establishments, the limited capabilities and short duration of operation are recognized by less stringent requirements for surface characteristics.

12 VAC 5-421-2800. Outdoor Areas - Surface Characteristics.

6-102.11

- A. The outdoor walking and driving areas shall be surfaced with concrete, asphalt, or gravel or other materials that have been effectively treated to minimize dust, facilitate maintenance, and prevent muddy conditions.
- B. Exterior surfaces of buildings and mobile food establishments shall be of weather-resistant materials and shall comply with law.
- C. Outdoor storage areas for refuse, recyclables, or returnables shall be of materials specified under 12 VAC 5-421-2600 and 12 VAC 5-421-2610.

The requirements concerning surface characteristics of outdoor areas are intended to facilitate maintenance and minimize the accumulation of dust and mud on walking and driving areas, provide durable exterior building surfaces, and prevent the attracting, harboring, or breeding of insects, rodents, and other pests where refuse, recyclables, or returnables are stored.

Part VI

Physical Facilities

Article 2

Design, Construction, and Installation

12 VAC 5-421-2810. Floors, Walls, and Ceilings - Cleanability.

6-201.11

- A. Except as specified under 12 VAC 5-421-2840, the floors, floor coverings, walls, wall coverings, and ceilings shall be designed, constructed, and installed so they are smooth and easily cleanable, except that antislip floor coverings or applications may be used for safety reasons.
- B. In lieu of subsection A of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

12 VAC 5-421-2820. Floors, Walls, and Ceilings, Utility Lines.

6-201.12

- A. Utility service lines and pipes may not be unnecessarily exposed.
- B. Exposed utility service lines and pipes shall be installed so they do not obstruct or prevent cleaning of the floors, walls, or ceilings.
 - C. Exposed horizontal utility service lines and pipes may not be installed on the floor.
- D. In lieu of subsections A through C of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

Cleanability 12 VAC 5-421-2810 Floors, Walls, and Ceilings. 12 VAC 5-421-2820 Floors, Walls, and Ceilings, Utility Lines.

Floors that are of smooth, durable construction and that are nonabsorbent are more easily cleaned. Requirements and restrictions regarding floor coverings, utility lines, and floor/wall junctures are intended to ensure that regular and effective cleaning is possible and that insect and rodent harborage is minimized.

12 VAC 5-421-2830. Floor and Wall Junctures, Coved, and Enclosed or Sealed. **6-201.13**

A. In food establishments in which cleaning methods other than water flushing are used for cleaning floors, the floor and wall junctures shall be coved and closed to no larger than 1/32 inch (1 mm). However, this subsection shall not apply to floor wall junctures in bed and breakfast facilities serving 18 or fewer customers.

B. The floors in food establishments in which water flush cleaning methods are used shall be provided with drains and be graded to drain, and the floor and wall junctures shall be coved and sealed.

When cleaning is accomplished by spraying or flushing, coving and sealing of the floor/wall junctures is required to provide a surface that is conducive to water flushing. Grading of the floor to drain allows liquid wastes to be quickly carried away, therebypreventing pooling which could attract pests such as insects and rodents or contribute to problems with certain pathogens such as **Listeria monocytogenes**.

12 VAC 5-421-2840. Floor Carpeting, Restrictions and Installation.

6-201.14

A. A floor covering such as carpeting or similar material may not be installed as a floor covering in food preparation areas, walk-in refrigerators, warewashing areas, toilet room areas where handwashing

lavatories, toilets, and urinals are located, refuse storage rooms, or other areas where the floor is subject to moisture, flushing, or spray cleaning methods.

- B. If carpeting is installed as a floor covering in areas other than those specified under Subsection A of this section, it shall be:
 - 1. Securely attached to the floor with a durable mastic, by using a stretch and tack method, or by another method; and
 - 2. Installed tightly against the wall under the coving or installed away from the wall with a space between the carpet and the wall and with the edges of the carpet secured by metal stripping or some other means.
- C. In lieu of subsections A and B of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

Requirements and restrictions regarding floor carpeting are intended to ensure that regular and effective cleaning is possible and that insect harborage is minimized. The restrictions for areas not suited for carpeting materials are designed to ensure cleanability of surfaces where accumulation of moisture or waste is likely.

12 VAC 5-421-2850. Floor Covering, Mats and Duckboards.

6-201.15

- A. Mats and duckboards shall be designed to be removable and easily cleanable.
- B. In lieu of subsection A of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

Requirements regarding mats and duckboards are intended to ensure that regular and effective cleaning is possible and that accumulation of dirt and waste is prevented.

12 VAC 5-421-2860. Wall and Ceiling Coverings and Coatings.

6-201.16

- A. Wall and ceiling covering materials shall be attached so that they are easily cleanable.
- B. Except in areas used only for dry storage, concrete, porous blocks, or bricks used for indoor wall construction shall be finished and sealed to provide a smooth, nonabsorbent, easily cleanable surface.

C. In lieu of subsections A and B of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

12 VAC 5-421-2870. Walls and Ceilings, Attachments.

6-201.17

- A. Except as specified in Subsection B of this section, attachments to walls and ceilings such as light fixtures, mechanical room ventilation system components, vent covers, wall mounted fans, decorative items, and other attachments shall be easily cleanable.
- B. In a consumer area, wall and ceiling surfaces and decorative items and attachments that are provided for ambiance need not meet this requirement if they are kept clean.
- C. In lieu of subsection A of this section, floors, walls, and ceilings in bed and breakfast facilities serving 18 or fewer customers shall be in good repair and kept clean.

12 VAC 5-421-2880. Walls and Ceilings, Studs, Joists, and Rafters.

6-201.18

Studs, joists, and rafters may not be exposed in areas subject to moisture. This requirement does not apply to temporary food establishments.

12 VAC 5-421-2860 Wall and Ceiling Coverings and Coatings. 12 VAC 5-421-2870 Walls and Ceilings, Attachments. 12 VAC 5-421-2880 Walls and Ceilings, Studs, Joists, and Rafters.

Walls and ceilings that are of smooth construction, nonabsorbent, and in good repair can be easily and effectively cleaned. Special requirements related to the attachment of accessories and exposure of wall and ceiling studs, joists, and rafters are intended to ensure the cleanability of these surfaces.

12 VAC 5-421-2890. Light Bulbs, Protective Shielding.

6-202.11

- A. Except as specified in Subsection B of this section, light bulbs shall be shielded, coated, or otherwise shatter-resistant in areas where there is exposed food; clean equipment, utensils, and linens; or unwrapped single-service and single-use articles.
- B. Shielded, coated, or otherwise shatter-resistant bulbs need not be used in areas used only for storing food in unopened packages, if:
 - 1. The integrity of the packages can not be affected by broken glass falling onto them; and

- 2. The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.
- C. An infrared or other heat lamp shall be protected against breakage by a shield surrounding and extending beyond the bulb so that only the face of the bulb is exposed.

Shielding of light bulbs helps prevent breakage. Light bulbs that are shielded, coated, or otherwise shatter-resistant are necessary to protect exposed food, clean equipment, utensils and linens, and unwrapped single-service and single-use articles from glass fragments should the bulb break.

12 VAC 5-421-2900. Heating, Ventilating, Air Conditioning System Vents. **6-202.12**

Heating, ventilating, and air conditioning systems shall be designed and installed so that make-up air intake and exhaust vents do not cause contamination of food, food-contact surfaces, equipment, or utensils.

Heating and air conditioning system vents that are not properly designed and located may be difficult to clean and result in the contamination of food, food preparation surfaces, equipment, or utensils by dust or other accumulated soil from the exhaust vents.

12 VAC 5-421-2910. Insect Control Devices, Design and Installation. **6-202.13**

A. Insect control devices that are used to electrocute or stun flying insects shall be designed to retain the insect within the device.

- B. Insect control devices shall be installed so that:
 - 1. The devices are not located over a food preparation area; and
 - 2. Dead insects and insect fragments are prevented from being impelled onto or falling on exposed food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles.

Insect electrocution devices are considered supplemental to good sanitation practices in meeting the Code requirement for controlling the presence of flies and other insects in a food establishment.

Improper design of the device and dead insect collection tray could allow dead insect parts and injured insects to escape, rendering the device itself a source of contamination.

Exposed food and food-contact surfaces must be protected from contamination by insects or insect parts. Installation of the device over food preparation areas or in close proximity to exposed food and/or food-contact surfaces could allow dead insects and/or insect parts to be impelled by the electric charge, fall, or be blown from the device onto food or food-contact surfaces.

12 VAC 5-421-2920. Toilet Rooms, Enclosed.

6-202.14

A toilet room located on the premises shall be completely enclosed and provided with a tight-fitting and self-closing door except that this requirement does not apply to a toilet room that is located outside a food establishment and does not open directly into the food establishment such as a toilet room that is provided by the management of a shopping mall.

Completely enclosed toilet facilities minimize the potential for the spread of disease by the movement of flies and other insects between the toilet facility and food preparation areas.

12 VAC 5-421-2930. Outer Openings, Protected.

6-202.15

- A. Except as specified in Subsections B, C, and E and under Subsection D of this section, outer openings of a food establishment shall be protected against the entry of insects and rodents by:
 - 1. Filling or closing holes and other gaps along floors, walls and ceilings;
 - 2. Closed, tight-fitting windows; and
 - 3. Solid self-closing, tight-fitting doors.
- B. Subsection A of this section does not apply if a food establishment opens into a larger structure, such as a mall, airport, or office building, or into an attached structure, such as a porch, and the outer openings from the larger or attached structure are protected against the entry of insects and rodents.
 - C. Exterior doors used as exits need not be self-closing if they are:
 - 1. Solid and tight-fitting;
 - 2. Designated for use only when an emergency exists, by the fire protection authority that has jurisdiction over the food establishment; and

- 3. Restricted so they are not used for entrance or exit from the building for purposes other than the designated emergency exit use.
- D. Except as specified in Subsection B and E of this section, if the windows or doors of a food establishment, or of a larger structure within which a food establishment is located, are kept open for ventilation or other purposes or a temporary food establishment is not provided with windows and doors as specified under Subsection A of this section, the openings shall be protected against the entry of insects and rodents by:
 - 1. 16 mesh to 1 inch (16 mesh to 25.4mm) screens;
 - 2. Properly designed and installed air curtains; or
 - 3. Other effective means.
- E. Subsection D of this section does not apply if flying insects and other pests are absent due to the location of the establishment, the weather, or other limiting condition.

Insects and rodents are vectors of disease-causing microorganisms which may be transmitted to humans by contamination of food and food-contact surfaces. The presence of insects and rodents is minimized by protecting outer openings to the food establishment.

In the National Fire Protection Association's NFPA 101, Life Safety Code®, 1994 Edition, doors to exit enclosures such as stairs, horizontal exits, or exit passageways are required to be self closing. The Life Safety Code does not require exterior doors used as exits to be self closing, but they can be.

The intent of Subparagraph 12 VAC 5-421-2930(A)(3) is to protect food establishments from the entry of insects and rodents by keeping doors closed when not in use. Self-closing devices allow a door to return to its closed position after use. If an exterior door is not routinely used for entry or exit because its use is restricted by the fire protection authority for emergency use only, it is not a portal for the entry of pests and does not need a self-closing device. Doors not requiring a self-closing device include exterior emergency exit doors that open into a public way from a fire and that meet the criteria in \P 12 VAC 5-421-2930(C).

12 VAC 5-421-2940. Exterior Walls and Roofs, Protective Barrier.

6-202.16

Perimeter walls and roofs of a food establishment shall effectively protect the establishment from the weather and the entry of insects, rodents, and other animals.

Walls and roofs provide a barrier to protect the interior and foods from the weather, windblown dirt and debris, and flying insects.

12 VAC 5-421-2950. Outdoor Food Vending Areas, Overhead Protection. **6-202.17**

If located outside, a machine used to vend food shall be provided with overhead protection except that machines vending canned beverages need not meet this requirement.

The potential for contamination from airborne dust and particulates or inclement weather is present in outside areas. Overhead protection minimizes the potential for contamination of food under such conditions.

12 VAC 5-421-2960. Outdoor Servicing Areas, Overhead Protection. **6-202.18**

Servicing areas shall be provided with overhead protection except that areas used only for the loading of water or the discharge of sewage and other liquid waste, through the use of a closed system of hoses, need not be provided with overhead protection.

Pooled water, which may result if overhead protection is not provided for outdoor servicing areas, attracts wild animals and birds and creates a condition suitable for the breeding of insects.

12 VAC 5-421-2970. Outdoor Walking and Driving Surfaces, Graded to Drain. **6-202.19**

Exterior walking and driving surfaces shall be graded to drain.

If foot traffic is allowed to occur from undrained areas, contamination will be tracked into the establishment. Surfaces graded to drain minimize these conditions. Pooled water on exterior walking and driving surfaces may also attract rodents and breed insects.

12 VAC 5-421-2980. Outdoor Refuse Areas, Curbed and Graded to Drain. **6-202.110**

Outdoor refuse areas shall be constructed in accordance with law and shall be curbed and graded to drain to collect and dispose of liquid waste that results from the refuse and from cleaning the area and waste receptacles.

If refuse areas are not graded properly, waste water will pool and attract insects and rodents.

12 VAC 5-421-2990. Private Homes and Living or Sleeping Quarters, Use Prohibition. **6-202.111**

A private home, a room used as living or sleeping quarters, or an area directly opening into a room used as living or sleeping quarters may not be used for conducting food establishment operations.

12 VAC 5-421-3000. Living or Sleeping Quarters, Separation.

6-202.112

Living or sleeping quarters located on the premises of a food establishment such as those provided for lodging registration clerks or resident managers shall be separated from rooms and areas used for food establishment operations by complete partitioning and solid self-closing doors.

12 VAC 5-421-2990 Private Homes and Living or Sleeping
Quarters, Use Prohibited.
12 VAC 5-421-3000 Living or Sleeping Quarters, Separation.

Areas or facilities that are not compatible with sanitary food establishment operations must be located and/or separated from other areas of the establishment to preclude potential contamination of food and food-contact surfaces from poisonous or toxic materials, dust or debris, the presence of improperly designed facilities and equipment, and the traffic of unauthorized and/or unnecessary persons or pets.

Further, Article IV of the Amendments to the U.S. Constitution ensures the right of persons to be secure in their homes against unreasonable search and seizure. This provision could hinder the regulatory authority's access to conduct routine inspections of a food establishment operated in the living area of a private home. A search warrant may be the only mechanism by which to gain entry; yet, it may be difficult to obtain and might not authorize the necessary inspectional activities.

Part VI

Physical Facilities

Article 3

Numbers and Capacities

12 VAC 5-421-3010. Handwashing Lavatories, Minimum Number.

6-301.10

Handwashing lavatories shall be provided as specified under 12 VAC 5-421-2230.

Refer to the public health reason for § 12 VAC 5-421-2230.

12 VAC 5-421-3020. Handwashing Cleanser, Availability.

6-301.11

Each handwashing lavatory or group of 2 adjacent lavatories shall be provided with a supply of hand cleaning liquid, powder, or bar soap.

Hand cleanser must always be present to aid in reducing microorganisms and particulate matter found on hands.

12 VAC 5-421-3030. Hand Drying Provision.

6-301.12

Each handwashing lavatory or group of adjacent lavatories shall be provided with:

- 1. Individual, disposable towels;
- 2. A continuous towel system that supplies the user with a clean towel; or
- 3. A heated-air hand drying device.

Provisions must be provided for hand drying so that employees will not dry their hands on their clothing or other unclean materials.

12 VAC 5-421-3040. Handwashing Aids and Devices, Use Restrictions.

6-301.13

A sink used for food preparation or utensil washing may not be provided with the handwashing aids and devices required for a handwashing lavatory as specified under 12 VAC 5-421-3020 and 12 VAC 5-421-3030 and 12 VAC 5-421-2650 C.

12 VAC 5-421-3045. Handwashing Signage.

6-301.14

A sign or poster that notifies food employees to wash their hands shall be provided at all handwashing lavatories used by food employees and shall be clearly visible to food employees.

A sign or poster is required to remind food employees to wash their hands.

12 VAC 5-421-3050. Disposable Towels, Waste Receptacle.

6-301.20

A handwashing lavatory or group of adjacent lavatories that is provided with disposable towels shall be provided with a waste receptacle as specified under 12 VAC 5-421-2650 C.

Waste receptacles at handwashing lavatories are required for the collection of disposable towels so that the paper waste will be contained, will not contact food directly or indirectly, and will not become an attractant for insects or rodents.

12 VAC 5-421-3060. Toilets and Urinals, Minimum Number.

6-302.10

Toilets and urinals shall be provided as specified under 12 VAC 5-421-2240.

Refer to the public health reason for § 12 VAC 5-421-2240.

12 VAC 5-421-3070. Toilet Tissue, Availability.

6-302.11

A supply of toilet tissue shall be available at each toilet.

To minimize hand contact with fecal waste, toilet tissue is necessary for hygienic cleaning following use of toilet facilities. Toilet tissue must be supplied to meet the demand.

12 VAC 5-421-3080. Lighting, Intensity.

6-303.11

The light intensity shall be:

- 1. At least 10 foot candles (110 lux) at a distance of 30 inches (75 cm) above the floor, in walk-in refrigeration units and dry food storage areas and in other areas and rooms during periods of cleaning;
- 2. At least 20 foot candles (220 lux):
 - a. At a surface where food is provided for consumer self-service such as buffets and salad bars or where fresh produce or packaged foods are sold or offered for consumption;
 - b. Inside equipment such as reach-in and under-counter refrigerators;
 - c. At a distance of 30 inches (75 cm) above the floor in areas used for handwashing, warewashing, and equipment and utensil storage, and in toilet rooms; and
- 3. At least 50 foot candles (540 lux) at a surface where a food employee is working with food or working with utensils or equipment such as knives, slicers, grinders, or saws where employee safety is a factor.

Lighting levels are specified so that sufficient light is available to enable employees to perform certain functions such as reading labels; discerning the color of substances; identifying toxic materials; recognizing the condition of food, utensils, and supplies; and safely conducting general food establishment operations and clean-up. Properly distributed light makes the need for cleaning apparent by making accumulations of soil conspicuous.

12 VAC 5-421-3090. Ventilation, Mechanical.

6-304.11

If necessary to keep rooms free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes, mechanical ventilation of sufficient capacity shall be provided.

When mechanical ventilation is necessary, it must have adequate capacity to ensure that soiling of walls, ceilings, and other equipment is minimized; obnoxious odors or toxic fumes are effectively removed; and no hazards or nuisances involving accumulation of fats, oils, and similar wastes are created.

Balancing of the exhaust and make-up air must be ensured so that the system can operate efficiently.

12 VAC 5-421-3100. Dressing Areas and Lockers, Designation.

6-305.11

- A. Dressing rooms or dressing areas shall be designated if employees routinely change their clothes in the establishment.
- B. Lockers or other suitable facilities shall be provided for the orderly storage of employees' clothing and other possessions.

Street clothing and personal belongings can contaminate food, food equipment, and food-contact surfaces. Proper storage facilities are required for articles such as purses, coats, shoes, and personal medications.

12 VAC 5-421-3110. Service Sinks, Availability.

6-306.10

A service sink or curbed cleaning facility shall be provided as specified under 12 VAC 5-421-2250.

A service sink or curbed facility is required so that the cleanliness of the food establishment can be maintained, attractants for insects and rodents minimized, and contamination of food and equipment by accumulated soil prevented. Liquid wastes generated during cleaning must be disposed of in a sanitary manner to preclude contamination of food and food equipment. A service sink is provided to prevent the improper disposal of wastes into other sinks such as food preparation and handwashing sinks.

Part VI

Physical Facilities

Article 4

Location and Placement

12 VAC 5-421-3120. Handwashing Lavatories, Conveniently Located. **6-401.10**

A. Handwashing lavatories shall be conveniently located as specified under 12 VAC 5-421-2280.

B. In lieu of subsection A of this section, approved dispensers, soap and single-use paper towels may be made available to accommodate hand washing in bed and breakfast kitchens serving 18 or less customers.

Facilities must be located in or adjacent to toilet rooms and convenient to the different work stations of the food employee for proper and routine handwashing to prevent contamination of the food and food-contact surfaces.

12 VAC 5-421-3130. Toilet Rooms, Convenience and Accessibility. **6-402.11**

Toilet rooms shall be conveniently located and accessible to employees during all hours of operation. Toilet rooms intended for use by customers shall not necessitate travel through food preparation or handling areas.

Toilet rooms must be conveniently accessible to food employees at all times to encourage employee use of appropriate facilities for the disposing of human wastes as needed followed by the washing of hands.

12 VAC 5-421-3140. Employee Accommodations, Designated Areas. **6-403.11**

A. Areas designated for employees to eat, drink, and use tobacco shall be located so that food, equipment, linens, and single-service and single-use articles are protected from contamination.

B. Lockers or other suitable facilities shall be located in a designated room or area where contamination of food, equipment, utensils, linens, and single-service and single-use articles can not occur.

Because employees could introduce pathogens to food by hand-to-mouth-to-food contact and because street clothing and personal belongings carry contaminants, areas designated to accommodate employees' personal needs must be carefully located. Food, food equipment and utensils, clean linens, and single-service and single-use articles must not be in jeopardy of contamination from these areas.

12 VAC 5-421-3150. Distressed Merchandise, Segregation and Location. **6-404.11**

Products that are held by the permit holder for credit, redemption, or return to the distributor, such as damaged, spoiled, or recalled products, shall be segregated and held in designated areas that are separated from food, equipment, utensils, linens, and single-service and single-use articles.

Products which are damaged, spoiled, or otherwise unfit for sale or use in a food establishment may become mistaken for safe and wholesome products and/or cause contamination of other foods, equipment, utensils, linens, or single-service or single-use articles. To preclude this, separate and segregated areas must be designated for storing unsalable goods.

12 VAC 5-421-3160. Refuse, Recyclables, and Returnables - Receptacles, Waste Handling Units, and Designated Storage Areas. **6-405.10**

Units, receptacles, and areas designated for storage of refuse and recyclable and returnable containers shall be located as specified under 12 VAC 5-421-2680.

Waste materials and empty product containers are unclean and can be an attractant to insects and rodents. Food, equipment, utensils, linens, and single-service and single-use articles must be protected from exposure to filth and unclean conditions and other contaminants. This Code provision addresses these concerns by requiring the facility to be segregated, to be located to allow cleaning of adjacent areas, and to preclude creation of a nuisance.

Part VI

Physical Facilities

Article 5

Maintenance and Operation

12 VAC 5-421-3170. Repairing.

6-501.11

The physical facilities shall be maintained in good repair.

Poor repair and maintenance compromises the functionality of the physical facilities. This requirement is intended to ensure that the physical facilities are properly maintained in order to serve their intended purpose.

12 VAC 5-421-3180. Cleaning, Frequency and Restrictions.

6-501.12

- A. The physical facilities shall be cleaned as often as necessary to keep them clean.
- B. Cleaning shall be done during periods when the least amount of food is exposed such as after closing. This requirement does not apply to cleaning that is necessary due to a spill or other accident.

Cleaning of the physical facilities is an important measure in ensuring the protection and sanitary preparation of food. A regular cleaning schedule should be established and followed to maintain the facility in a clean and sanitary manner. Primary cleaning should be done at times when foods are in protected storage and when food is not being served or prepared.

12 VAC 5-421-3190. Cleaning Floors, Dustless Methods.

6-501.13

- A. Except as specified in Subsection B of this section, only dustless methods of cleaning shall be used, such as wet cleaning, vacuum cleaning, mopping with treated dust mops, or sweeping using a broom and dust-arresting compounds.
 - B. Spills or drippage on floors that occur between normal floor cleaning times may be cleaned:
 - 1. Without the use of dust-arresting compounds; and
 - 2. In the case of liquid spills or drippage, with the use of a small amount of absorbent compound such as sawdust or diatomaceous earth applied immediately before spot cleaning.

Dustless floor cleaning methods must be used so that food; equipment, utensils, and linens; and single-service and single-use articles are not contaminated.

12 VAC 5-421-3200. Cleaning Ventilation Systems, Nuisance and Discharge Prohibition.

6-501.14

A. Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.

B. If vented to the outside, ventilation systems may not create a public health hazard or nuisance or unlawful discharge.

Both intake and exhaust ducts can be a source of contamination and must be cleaned regularly. Filters that collect particulate matter must be cleaned or changed frequently to prevent overloading of the filter. Outside areas under or adjacent to exhaust duct outlets at the exterior of the building must be maintained in a clean and sanitary manner to prevent pest attraction.

12 VAC 5-421-3210. Cleaning Maintenance Tools, Preventing Contamination.* 6-501.15

Food preparation sinks, handwashing lavatories, and warewashing equipment may not be used for the cleaning of maintenance tools, the preparation or holding of maintenance materials, or the disposal of mop water and similar liquid wastes.

Maintenance tools used to repair the physical facilities must be cleaned in a separate area to prevent contamination of food and food preparation and warewashing areas.

12 VAC 5-421-3220. Drying Mops.

6-501.16

After use, mops shall be placed in a position that allows them to air-dry without soiling walls, equipment, or supplies.

Mops can contaminate food and food preparation areas if not properly cleaned and stored after use. Mops should be cleaned and dried in a sanitary manner away from food flow areas.

12 VAC 5-421-3230. Absorbent Materials on Floors, Use Limitation. **6-501.17**

Except as specified in 12 VAC 5-421-3190 B, sawdust, wood shavings, granular salt, baked clay, diatomaceous earth, or similar materials may not be used on floors.

Cleanliness of the food establishment is important to minimize attractants for insects and rodents, aid in preventing the contamination of food and equipment, and prevent nuisance conditions. A clean and orderly food establishment is also conducive to positive employee attitudes which can lead to increased attention to personal hygiene and improved food preparation practices. Use of specified cleaning procedures is important in precluding avoidable contamination of food and equipment and nuisance conditions.

Temporary floor coverings such as sawdust can contaminate food, attract insects and rodents, and become a nuisance to the food operation.

12 VAC 5-421-3240. Maintaining and Using Handwashing Lavatories. **6-501.18**

Handwashing lavatories shall be kept clean, and maintained and used as specified under 12 VAC 5-421-2310.

Handwashing facilities are critical to food protection and must be maintained in operating order at all times so they will be used.

Refer also to the public health reason for § 12 VAC 5-421-2310.

12 VAC 5-421-3250. Closing Toilet Room Doors.

6-501.19

Toilet room doors as specified under 12 VAC 5-421-2920 shall be kept closed except during cleaning and maintenance operations unless otherwise required by other regulations or law.

Toilet room doors must remain closed except during cleaning operations to prevent insect and rodent entrance and the associated potential for the spread of disease.

12 VAC 5-421-3260. Using Dressing Rooms and Lockers.

6-501.110

- A. Dressing rooms shall be used by employees if the employees regularly change their clothes in the establishment.
- B. Lockers or other suitable facilities shall be used for the orderly storage of employee clothing and other possessions.

Street clothing and personal belongings can contaminate food, food equipment, and food preparation surfaces and consequently must be stored in properly designated areas or rooms.

12 VAC 5-421-3270. Controlling Pests.*

6-501.111

The presence of insects, rodents, and other pests shall be controlled to minimize their presence on the premises by:

- 1. Routinely inspecting incoming shipments of food and supplies;^N
- 2. Routinely inspecting the premises for evidence of pests; N

- 3. Using methods, if pests are found, such as trapping devices or other means of pest control as specified under 12 VAC 5-421-3360, 12 VAC 5-421-3440, and 12 VAC 5-421-3450; and
- 4. Eliminating harborage conditions. N

Insects and other pests are capable of transmitting disease to man by contaminating food and food-contact surfaces. Effective measures must be taken to control their presence in food establishments.

12 VAC 5-421-3280. Removing Dead or Trapped Birds, Insects, Rodents, and Other Pests. **6-501.112**

Dead or trapped birds, insects, rodents, and other pests shall be removed from control devices and the premises at a frequency that prevents their accumulation, decomposition, or the attraction of pests.

Dead rodents, birds, and insects must be removed promptly from the facilities to ensure clean and sanitary facilities and to preclude exacerbating the situation by allowing carcasses to attract other pests.

12 VAC 5-421-3290. Storing Maintenance Tools.

6-501.113

Maintenance tools such as brooms, mops, vacuum cleaners, and similar items shall be:

- 1. Stored so they do not contaminate food, equipment, utensils, linens, and single-service and single-use articles; and
- 2. Stored in an orderly manner that facilitates cleaning the area used for storing the maintenance tools.

Brooms, mops, vacuum cleaners, and other maintenance equipment can contribute contamination to food and food-contact surfaces. These items must be stored in a manner that precludes such contamination.

To prevent harborage and breeding conditions for rodents and insects, maintenance equipment must be stored in an orderly fashion to permit cleaning of the area.

12 VAC 5-421-3300. Maintaining Premises, Unnecessary Items and Litter.

6-501.114

The premises shall be free of:

1. Items that are unnecessary to the operation or maintenance of the establishment such as equipment that is nonfunctional or no longer used; and

2. Litter.

The presence of unnecessary articles, including equipment which is no longer used, makes regular and effective cleaning more difficult and less likely. It can also provide harborage for insects and rodents.

Areas designated as equipment storage areas and closets must be maintained in a neat, clean, and sanitary manner. They must be routinely cleaned to avoid attractive or harborage conditions for rodents and insects.

12 VAC 5-421-3310. Prohibiting Animals.*

6-501.115

- A. Except as specified in Subsection B and C of this section, live animals may not be allowed on the premises of a food establishment.
- B. Live animals may be allowed in the following situations if the contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result:
 - 1. Edible fish or decorative fish in aquariums, shellfish or crustacea on ice or under refrigeration, and shellfish and crustacea in display tank systems;
 - 2. Patrol dogs accompanying police or security officers in offices and dining, sales, and storage areas, and sentry dogs running loose in outside fenced areas;
 - 3. In areas that are not used for food preparation and that are usually open for customers, such as dining and sales areas, service animals that are controlled by the disabled employee or person, if a health or safety hazard will not result from the presence or activities of the service animal; and
 - 4. Pets in the common dining areas of group residences at times other than during meals if:
 - a. Effective partitioning and self-closing doors separate the common dining areas from food storage or food preparation areas,
 - b. Condiments, equipment, and utensils are stored in enclosed cabinets or removed from the common dining areas when pets are present, and

- c. Dining areas including tables, countertops, and similar surfaces are effectively cleaned before the next meal service.
- 5. In areas that are not used for food preparation, storage, sales, display, or dining, in which there are caged animals or animals that are similarly restricted, such as in a variety store that sells pets or a tourist park that displays animals.
- C. Live or dead fish bait may be stored if contamination of food; clean equipment, utensils, and linens; and unwrapped single-service and single-use articles can not result.
- D. In bed and breakfast facilities serving 18 or fewer customers, live animals shall be allowed in the facility but shall not be fed using the same equipment or utensils that are used to feed humans.

Animals carry disease-causing organisms and can transmit pathogens to humans through direct and/or indirect contamination of food and food-contact surfaces. The restrictions apply to live animals with limited access allowed only in specific situations and under controlled conditions and to the storage of live and dead fish bait. Employees with support animals are required under § 12 VAC 5-421-160 to wash their hands after each contact with animals to remove bacteria and soil.

Animals shed hair continuously and may deposit liquid or fecal waste, creating the need for vigilance and more frequent and rigorous cleaning efforts.

The definition for "service animal" is adapted from 28 CFR 36.104 adopted pursuant to the Americans with Disabilities Act (ADA) of 1990 (42 U.S.C. 12101 et seq.). A service animal performs some of the functions that persons with a disability cannot perform for themselves, such as those provided by "seeing eye dogs"; alerting persons with hearing impairments to sounds; pulling wheelchairs or carrying and picking up things for persons with mobility impairments; and assisting persons with mobility impairments with balance. A service animal is not considered to be a pet.

Under Title III of the ADA, privately owned businesses that serve the public are prohibited from discriminating against individuals with diabilities. The ADA requires these businesses to allow people with disabilities to bring their service animals onto business premises in whatever areas customers are generally allowed. Some, but not all, service animals wear special collars or harnesses. Some, but not all, are licensed or certified and have identification papers.

Decisions regarding a food employee or applicant with a disability who needs to use a service animal should be made on a case-by-case basis. An employer must comply with health and safety requirements, but is obligated to consider whether there is a reasonable accommodation that can be made. Guidance is available from the U.S. Department of Justice, Civil Rights Division, Disability Rights Section or the U.S. Equal Employment Opportunity Commission, the

federal agency which has the lead in these matters, in documents such as, "Commonly Asked Questions About Service Animals in Places of Business"; "The Americans with Disabilities Act Questions and Answers"; "A Guide to Disability Rights Laws"; and "Americans with Disabilities Act Title III Technical Assistance Manual, 1994 Supplement." The ADA Information Line is 800-514-0301 (voice) or 800-514-0383 (TDD) and the Internet Home Page address is http://www.usdoj.gov/crt/ada/adahom1.htm.

Part VII

Poisonous or Toxic Materials

Article 1

Labeling and Identification

12 VAC 5-421-3320. Original Containers - Identifying Information, Prominence.*

7-101.11

Containers of poisonous or toxic materials and personal care items shall bear a legible manufacturer's label.

The accidental contamination of food or food-contact surfaces can cause serious illness. Prominent and distinct labeling helps ensure that poisonous and toxic materials including personal care items are properly used.

12 VAC 5-421-3330. Working Containers - Common Name.*

Working containers used for storing poisonous or toxic materials such as cleaners and sanitizers taken from bulk supplies shall be clearly and individually identified with the common name of the material.

It is common practice in food establishments to purchase many poisonous or toxic materials including cleaners and sanitizers in bulk containers. Working containers are frequently used to convey these materials to areas where they will be used, resulting in working containers being stored in different locations in the establishment. Identification of these containers with the common name of the material helps prevent the dangerous misuse of the contents.

Part VII

Poisonous or Toxic Materials

Article 2

Operational Supplies and Applications

12 VAC 5-421-3340. Storage, Separation.*

7-201.11

Poisonous or toxic materials shall be stored so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

- 1. Separating the poisonous or toxic materials by spacing or partitioning;^S
- 2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles. This subsection does not apply to equipment and utensil cleaners and sanitizers that are stored in warewashing areas for availability and convenience if the materials are stored to prevent contamination of food, equipment, utensils, linens, and single-service and single-use articles; and,
- 3. Detergents, sanitizers, related cleaning or drying agents and caustics, acids, polishes and other chemicals shall be stored separately from insecticides and rodenticides.

Separation of poisonous and toxic materials in accordance with the requirements of this section ensures that food, equipment, utensils, linens, and single-service and single-use articles are properly protected from contamination. For example, the storage of these types of materials directly above or adjacent to food could result in contamination of the food from spillage.

- A. Only those poisonous or toxic materials that are required for the operation and maintenance of a food establishment, such as for the cleaning and sanitizing of equipment and utensils and the control of insects and rodents, shall be allowed in a food establishment.^S
- B. Subsection A of this section does not apply to packaged poisonous or toxic materials that are for retail sale.

The presence in the establishment of poisonous or toxic materials that are not required for the maintenance and operation of the establishment represents an unnecessary risk to both employees and consumers.

Preserving food safety depends in part on the appropriate and proper storage and use of poisonous or toxic materials that are necessary to the maintenance and operation of a food establishment. Even those that are necessary can pose a hazard if they are used in a manner that contradicts the intended use of the material as described by the manufacturer on the material's label. If additional poisonous or toxic materials are present, there is an unwarranted increased potential for contamination due to improper storage (e.g., overhead spillage that could result in the contamination of food, food-contact surfaces, or food equipment) or inappropriate application.

12 VAC 5-421-3360. Conditions of Use.*

7-202.12

Poisonous or toxic materials shall be:

- 1. Used according to:
 - a. Law and this Chapter,
 - b. Manufacturer's use directions included in labeling, and, for a pesticide, manufacturer's label instructions that state that use is allowed in a food establishment,
 - c. The conditions of certification, if certification is required, for use of the pest control materials, and
 - d. Additional conditions that may be established by the regulatory authority; and
- 2. Applied so that:
 - a. A hazard to employees or other persons is not constituted, and

- b. Contamination including toxic residues due to drip, drain, fog, splash or spray on food, equipment, utensils, linens, and single-service and single-use articles is prevented, and for a restricted-use pesticide, this is achieved by:
 - (1) Removing the items,
 - (2) Covering the items with impermeable covers, or
 - (3) Taking other appropriate preventive actions, and
 - (4) Cleaning and sanitizing equipment and utensils after the application.
- 3. A restricted use pesticide shall be applied only by an applicator certified as defined in 7 USC 136(e) Certified Applicator, of the Federal Insecticide, Fungicide and Rodenticide Act, or a person under the direct supervision of a certified applicator.

Failure to properly use poisonous or toxic materials can be dangerous. Many poisonous or toxic materials have general use directions on their label. Failure to follow the stated instructions could result in injury to employees and consumers through direct contact or the contamination of food.

Particular precautions must be taken during the application of poisonous or toxic materials to prevent the contamination of food and other food-contact surfaces. Residues of certain materials are not discernible to the naked eye and present an additional risk to the employee and consumer.

Because of the toxicity of restricted-use pesticides, they can only be applied by certified operators. A certified operator would be aware of the dangers involved in the contamination of food and food-contact surfaces during the application of these materials. Improperly applied pesticides present health risks to employees as well as consumers and special precautions must be taken when restricted-use pesticides are applied.

12 VAC 5-421-3370. Poisonous or Toxic Material Containers.*

7-203.11

A container previously used to store poisonous or toxic materials may not be used to store, transport, or dispense food.

Use of poisonous or toxic material containers to store, transport, or dispense food is prohibited because of the potential for contamination of the food. The risk of serious medical consequences to anyone consuming food stored in these containers coupled with the lack of confidence that all of the material could or would be removed in the wash and sanitizing procedures are reasons for prohibiting this practice.

12 VAC 5-421-3380. Sanitizers, Criteria.*

7-204.11

Chemical sanitizers and other chemical antimicrobials applied to food-contact surfaces shall meet the requirements specified in 21 CFR 178.1010 sanitizing solutions.

Chemical sanitizers are included with poisonous or toxic materials because they may be toxic if not used in accordance with requirements listed in the Code of Federal Regulations (CFR). Large concentrations of sanitizer in excess of the CFR requirements can be harmful because residues of the materials remain. The CFR reference that is provided lists concentrations of sanitizers that are considered safe.

12 VAC 5-421-3390. Chemicals for Washing Fruits and Vegetables, Criteria.* **7-204.12**

Chemicals used to wash or peel raw, whole fruits and vegetables shall meet the requirements specified in 21 CFR 173.315 Chemicals used in washing or to assist in the lye peeling of fruits and vegetables.

12 VAC 5-421-3400. Boiler Water Additives, Criteria.*

7-204.13

Chemicals used as boiler water additives shall meet the requirements specified in 21 CFR 173.310 Boiler Water Additives.

12 VAC 5-421-3410. Drying Agents, Criteria.*

7-204.14

Drying agents used in conjunction with sanitization shall:

- 1. Contain only components that are listed as one of the following:
 - a. Generally recognized as safe for use in food as specified in 21 CFR 182 Substances Generally Recognized as Safe, or 21 CFR 184 Direct Food Substances Affirmed as Generally Recognized as Safe,
 - b. Generally recognized as safe for the intended use as specified in 21 CFR 186 Indirect Food Substances Affirmed as Generally Recognized as Safe,
 - c. Approved for use as a drying agent under a prior sanction specified in 21 CFR 181 Prior-Sanctioned Food Ingredients,
 - d. Specifically regulated as an indirect food additive for use as a drying agent as specified in 21 CFR Parts 175-178, or

- e. Approved for use as a drying agent under the threshold of regulation process established by 21 CFR 170.39 Threshold of regulation for substances used in food-contact articles; and
- 2. When sanitization is with chemicals, the approval required under Subsection 1 c or 1 e of this section or the regulation as an indirect food additive required under Subsection 4 1 d of this section, shall be specifically for use with chemical sanitizing solutions.

12 VAC 5-421-3390 Chemicals for Washing Fruits and Vegetables, Criteria.*
12 VAC 5-421-3400 Boiler Water Additives, Criteria.*
12 VAC 5-421-3410 Drying Agents, Criteria.*

If the sanitizer, chemical wash, boiler water additive, or drying agent used is not made up of components that are approved as food additives or generally recognized as safe, illness may result. This could be due to residues that may remain from the use of compounds such as unrecognized drying agents. This is why only those chemicals that are listed in the CFR can be used.

Chemicals that are not listed for these uses may be submitted for review by filing a Food Additive Petition. Sanitizers, wash chemicals, and drying agents are classified as food additives because of the possibility that they may end up in food. Therefore, they are subject to review before being used or listed in the CFR.

21 CFR section 173.315 specifically identifies chemicals that may be used in washing fruits and vegetables, but it does not specify any maximum level (2000 ppm or otherwise) of chemical usage for sodium hypochlorite. FDA acknowledges the use of sodium hypochlorite on fruits and vegetables and also allows calcium hypochlorite to be used interchangeably with sodium hypochlorite under 21 CFR 173.315.

12 VAC 5-421-3420. Lubricants - Incidental Food Contact, Criteria.* **7-205.11**

Lubricants shall meet the requirements specified in 21 CFR 178.3570 Lubricants with incidental food contact, if they are used on food-contact surfaces, on bearings and gears located on or within food-contact surfaces, or on bearings and gears that are located so that lubricants may leak, drip, or be forced into food or onto food-contact surfaces.

Lubricants used on food equipment may directly or indirectly end up in the food. Therefore, the lubricants used must be approved as food additives or generally recognized as safe and listed in the CFR. Lubricants that are not safe present the possibility of foodborne illness if they find their way into the food.

Restricted use pesticides specified under 12 VAC 5-421-3360 3shall meet the requirements specified in 40 CFR 152 Subpart I - Classification of Pesticides.

Open bait stations may result in the spillage of the poison being used. Also, it is easier for pests to transport the potentially toxic bait throughout the establishment. Consequently, the bait may end up on food-contact surfaces and ultimately in the food being prepared or served.

12 VAC 5-421-3440. Rodent Bait Stations.*

7-206.12

Rodent bait shall be contained in a covered, tamper-resistant bait station.

The use of tracking powder pesticides presents the potential for the powder to be dispersed throughout the establishment. Consequently, the powder could directly or indirectly contaminate food being prepared. This contamination could adversely affect both the safety and quality of the food and, therefore, tracking powder pesticides are not allowed.

12 VAC 5-421-3450. Tracking Powders, Pest Control and Monitoring.*

7-206.13

- A. A tracking powder pesticide may not be used in a food establishment.
- B. If used, a nontoxic tracking powder such as talcum or flour may not contaminate food, equipment, utensils, linens, and single-service and single-use articles.^N

12 VAC 5-421-3460. Medicines - Restriction and Storage.*

7-207.11

- A. Only those medicines that are necessary for the health of employees shall be allowed in a food establishment. This section does not apply to medicines that are stored or displayed for retail sale.
- B. Medicines that are in a food establishment for the employees' use shall be labeled as specified under 12 VAC 5-421-3320 and located to prevent the contamination of food, equipment, utensils, linens, and single-service and single-use articles.

Medicines that are not necessary for the health of employees present an unjustified risk to the health of other employees and consumers due to misuse and/or improper storage. There are circumstances that require employees or children in a day care center to have personal medications on hand in the establishment. To prevent misuse, personal medications must be labeled and stored in accordance with the requirements stated for poisonous or toxic materials.

Proper labeling and storage of medicines to ensure that they are not accidentally misused or otherwise contaminate food or food-contact surfaces.

12 VAC 5-421-3470. Refrigerated Medicines, Storage.*

7-207.12

Medicines belonging to employees or to children in a day care center that require refrigeration and are stored in a food refrigerator shall be:

- 1. Stored in a package or container and kept inside a covered, leakproof container that is identified as a container for the storage of medicines; and
- 2. Located so they are inaccessible to children.

Some employee medications may require refrigerated storage. If employee medications are stored in a food refrigerator, precautions must be taken to prevent the contamination of other items stored in the same refrigerator.

12 VAC 5-421-3480. First Aid Supplies, Storage.*

7-208.11

First aid supplies that are in a food establishment for the employees' use shall be:

- 1. Labeled as specified under 12 VAC 5-421-3320;^S and
- 2. Stored in a kit or a container that is located to prevent the contamination of food, equipment, utensils, and linens, and single-service and single-use articles. ^S

First aid supplies for employee use must be identified and stored in accordance with the requirements of this Code in order to preclude the accidental contamination of food, food equipment, and other food-contact surfaces.

12 VAC 5-421-3490. Other Personal Care Items, Storage.

7-209.11

Except as specified under 12 VAC 5-421-3470 and 12 VAC 5-421-3480, employees shall store their personal care items in facilities as specified under 12 VAC 5-421-3100 B.

Employee personal care items may serve as a source of contamination and may contaminate food, food equipment, and food-contact surfaces if they are not properly labeled and stored.

Part VII

Poisonous or Toxic Materials

Article 3

Stock and Retail Sale

12 VAC 5-421-3500. Storage and Display, Separation.*

7-301.11

Poisonous or toxic materials shall be stored and displayed for retail sale so they can not contaminate food, equipment, utensils, linens, and single-service and single-use articles by:

- 1. Separating the poisonous or toxic materials by spacing or partitioning; s and
- 2. Locating the poisonous or toxic materials in an area that is not above food, equipment, utensils, linens, and single-service or single-use articles.

Poisonous or toxic materials held for sale on store shelves or stored in stock rooms present a risk of contamination of food, equipment, utensils, linens, and single-service and single-use articles if not stored properly.

Part VIII

Compliance and Enforcement

Article 1

Chapter Applicability

12 VAC 5-421-3510. Public Health Protection.

8-101.10

A. The regulatory authority shall apply this regulation to promote its underlying purpose, as specified in 12 VAC 5-421-30, of safeguarding public health and ensuring that food is safe and unadulterated when offered to the consumer.

- B. In enforcing the provisions of this regulation, the regulatory authority shall assess existing facilities or equipment that were in use before the effective date of this Chapter based on the following considerations:
 - 1. Whether the facilities or equipment are in good repair and capable of being maintained in a sanitary condition;
 - 2. Whether food-contact surfaces comply with Subparts 12 VAC 5-421-960 through 1060;
 - 3. Whether the capacities of cooling, heating, and holding equipment are sufficient to comply with 12 VAC 5-421-1450; and
 - 4. The existence of a documented agreement with the permit holder that the facilities or equipment will be replaced as specified under 12 VAC 5-421-3750 7 or upgraded or replaced as specified under 12 VAC 5-421-3750 8.

12 VAC 5-421-3520. Preventing Health Hazards, Provision for Conditions Not Addressed. **8-102.10**

- A. If necessary to protect against public health hazards or nuisances, the regulatory authority may impose specific requirements in addition to the requirements contained in this regulation that are authorized by law.
- B. The regulatory authority shall document the conditions that necessitate the imposition of additional requirements and the underlying public health rationale. The documentation shall be provided to the permit applicant or permit holder and a copy shall be maintained in the regulatory authority's file for the food establishment.
- 12 VAC 5-421-3530. Application of Administrative Process Act.

The provisions of the Virginia Administrative Process Act (9.6.14:1) shall govern the procedures for rendering all case decisions, as defined in 9-6.14:4, and for issuing all orders and regulations promulgated pursuant to the authority of Title 35.1.

12 VAC 5-421-3540. The effective date of these regulations is March 1, 2002.

12 VAC 5-421-3550. Food Service Advisory Committee (FSAC).

The commissioner shall appoint a FSAC. He shall appoint to the FSAC as many members as he wishes, but a minimum of one individual each from the following: Department of Agriculture and Consumer Services; Department of Housing and Community Development; Department of Social Services; Virginia Hospitality and Travel Association; Virginia Retail Merchant's Association; Public at Large; Virginia Public Health Association; Virginia Environmental Health Association; Virginia Caterer's Association; Virginia Food Dealers Association; Consumer and/or Civic Organization Representative and an Environmental Health Specialist.

Ex-Officio -- Members shall be Director of the Division of Food and General Environmental Services and Director of Health Facilities Regulation.

Appointed Members of the FSAC shall serve at the discretion of the commissioner and shall make recommendation to the commissioner regarding food service policies, procedures and other food program operations. The FSAC shall meet at least annually.

12 VAC 5-421-3560. Exemptions to regulations.

The following are exempt from this chapter as defined in § 35.1-25 and § 35.1-26 of the Code of Virginia.

- A. General.
- 1. Boarding houses that do not accommodate transients;
- 2. Cafeterias operated by industrial plants for employees only;
- 3. Churches, fraternal, school and social organizations and volunteer fire departments and rescue squads which hold dinners and bazaars of not more than one time per week and not in excess of two days duration at which food prepared in homes of members or in the kitchen of the church or organization and is offered for sale to the public;
- 4. Grocery stores, including the delicatessen which is a part of a grocery store, selling exclusively for off-premises consumption and places manufacturing or selling packaged or canned goods.
- 5. Churches which serve meals for their members as a regular part of their religious observance.
- B. Certain Fairs, and Youth Activities. The governing body of any county, city or town may provide by ordinance that this part shall not apply to food booths at fairs and youth athletic activities, if such booths are promoted or sponsored by any political subdivision of the Commonwealth or by any

charitable nonprofit organization or group thereof. The ordinance shall provide that the director of the county, city, or town in which the fair and youth athletic activities are held, or a qualified person designated by the director, shall exercise such supervision of the sale of food as the ordinance may prescribe.

12 VAC 5-421-3570. Variances

The commissioner or his designee may grant a variance to these regulations by following the appropriate procedures set forth in this section.

- A. Requirements for a variance. The commissioner may grant a variance if he finds that the hardship imposed, which may be economic, outweighs the benefits that may be received by the public and that granting such a variance does not subject the public to unreasonable health risks or environmental pollution.
- B. Application for a variance. Any owner or permit holder who seeks a variance shall apply in writing within the time period specified in 12 VAC 5-421-4000. The request should be sent to the local health department. The application shall include:
 - 1. A citation to the regulation from which a variance is requested;
 - 2. The nature and duration of the variance requested;
 - 3. Any relevant analytical results including result of relevant tests conducted pursuant to the requirements of these regulations;
 - 4. Statements or evidence which establishes that the public health, welfare and environment would not be adversely affected if the variance were granted;
 - 5. Suggested conditions that might be imposed on the granting of a variance that would limit the detrimental impact on the public health and welfare;
 - 6. A HACCP plan if required as specified under 12 VAC 5-421-3620 A that includes the information specified under 12 VAC 5-421-3630 as it is relevant to the variance requested.
 - 7. Other information believed pertinent by the applicant; and
 - 8. Such other information as the district or local health department or commissioner may require.

12 VAC 5-421-3580. Evaluation of a Variance Application

- A. The commissioner shall act on any variance request submitted pursuant to 12 VAC 5-421-3570 B within 60 days of receipt of the request.
- B. In evaluating a variance application, the commissioner shall consider such factors as the following:
 - 1. The effect that such a variance would have on the operation of the food establishment.
 - 2. The cost and other economic considerations imposed by this requirement;
 - 3. The effect that such a variance would have on protection of the public health, safety, welfare and the environment;
 - 4. Such other factors as the commissioner, deputy commissioner, or director of the office of environmental services may deem appropriate.

12 VAC 5-421-3590. Disposition of a Variance Request

- A. The commissioner may grant the variance request and if the commissioner proposes to deny the variance he shall provide the owner or permit holder an opportunity to an informal hearing as provided in § 9-6.14:11 of the Code of Virginia. Following this opportunity for an informal hearing the commissioner may reject any application for a variance by sending a rejection notice to the applicant. The rejection notice shall be in writing and shall state the reasons for the rejection. A rejection notice constitutes a case decision.
- B. If the commissioner proposes to grant a variance request submitted pursuant to this part, the applicant shall be notified in writing of this decision. Such notice shall identify the variance, the food establishment involved, and shall specify the period of time for which the variance will be effective. Such notice shall provide that the variance will be terminated when the food establishment comes into compliance with the applicable regulation and may be terminated upon a finding by the commissioner that the food establishment has failed to comply with any requirements or schedules issued in conjunction with the variance. The effective date of the variance shall be as noted in the variance letter.
- C. All variances granted to any food establishment maybe transferable unless otherwise stated. Each variance shall be attached to the permit to which it is granted. Each variance is revoked when the permit to which it is attached is revoked.

- D. No owner or permit holder may challenge the terms or conditions of a variance after 30 calendar days have elapsed from the receipt of the variance.
- E. Each variance shall be posted prominently in a conspicuous place for public view and in close proximity to the permit to which it relates. Each variance is revoked when the permit to which it is attached is revoked, or if the permit is not revalidated or renewed.

Part VIII

Compliance and Enforcement

Article 2

Plan Submission and Approval

12 VAC 5-421-3600. Facility and Operating Plans - When Plans Are Required.

A permit applicant or permit holder shall submit to the regulatory authority properly prepared plans and specifications for review and approval before:

- 1. The construction of a food establishment;
- 2. The conversion of an existing structure for use as a food establishment; or
- 3. The remodeling of a food establishment or a change of type of food establishment or food operation as specified under 12 VAC 5-421-3710 3 if the regulatory authority determines that plans and specifications are necessary to ensure compliance with this regulation.

12 VAC 5-421-3610. Contents of the Plans and Specifications.

8-201.12

The plans and specifications for a food establishment, including a food establishment specified under 12 VAC 5-421-3620, shall include, as required by the regulatory authority based on the type of operation, type of food preparation, and foods prepared, the following information to demonstrate conformance with regulatory provisions:

- 1. Intended menu;
- 2. Anticipated volume of food to be stored, prepared, and sold or served;
- 3. Proposed layout, mechanical schematics, construction materials, and finish schedules;

- 4. Proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
- 5. Evidence that standard procedures that ensure compliance with the requirements of this chapter are developed or are being developed; and
- 6. Other information that may be required by the regulatory authority for the proper review of the proposed construction, conversion or modification, and procedures for operating a food establishment.

12 VAC 5-421-3610 Contents of the Plans and Specifications. 12 VAC 5-421-3650 Preoperational Inspections.

In conjunction with the Conference for Food Protection Plan Review committee, FDA has participated in developing a document that is intended to assist regulators in reviewing food establishment plans, and industry in understanding what is expected in the plan review process. For several years, this Plan Review Manual has been used in the FDA State Training Branch Plan Review courses. It was endorsed by the CFP at the Conference's 1998 meeting and continues to undergo expansion to address temporary food events. It can be accessed through http://www.fda.gov/~dms/prev-toc.html.

At the plan review stage, the regulatory authority may be dealing with an agent of the permit applicant who is seeking a building permit and who is not in a position to discuss plans for safely conducting the food operation. Nonetheless, the plan review step presents a unique opportunity to lay a foundation that enables the proposed operation to proactively sustain compliance with the Code over time. Standard operational procedures (SOPs) are a part of that foundation and ideally are developed in tandem with designing the facility. Consequently, as an integral part of the plan review process, discussion needs to occur about such procedures and their scope.

SOPs need to be developed by the time of the preoperational inspection and put into effect when the food operation begins. It is recommended that such procedures be written, available for reference by the person in charge, conveyed to the appropriate employees, and available for review by the regulatory authority during inspections. Operating procedures should include definitive practices and expectations that ensure that:

- (1) The transmission of foodborne disease is prevented by managing job applicants and food employees as specified under Subpart 2-201,
- (2) Food is received from approved sources as specified under § 12 VAC 5-421-270,

- (3) Food is managed so that the safety and integrity of the food from the time of delivery to the establishment throughout its storage, preparation, and transportation to the point of sale or service to the consumer is protected,
- (4) Potentially hazardous food is maintained, including freezing, cold holding, cooking, hot holding, cooling, reheating, and serving in conformance with the temperature and time requirements specified under Parts 3-4 and 3-5,
- (5) Warewashing is effective, including assurance that the chemical solutions and exposure times necessary for cleaning and sanitizing utensils and food-contact surfaces of equipment are provided as specified under Parts 4-6 and 4-7, and
- (6) Records that are specified under §§ 12 VAC 5-421-430, 12 VAC 5-421-440, and 12 VAC 5-421-2330 are retained for inspection.

During the plan review stage, the regulatory authority and a management representative of the proposed food establishment should discuss available training options that may be used to train food employees and the person in charge regarding food safety as it relates to their assigned duties. By the time of the preoperational inspection, operating procedures for training should include definitive practices and expectations of how the management of the proposed food establishment plans to comply with ¶ 12 VAC 5-421-70(L) of this Code which requires the person in charge to assure that food employees are properly trained in food safety as it relates to their assigned duties.

12 VAC 5-421-3620. When a HACCP Plan is Required.

8-201.13

- A. Before engaging in an activity that requires a HACCP plan, a permit applicant or permit holder shall submit to the regulatory authority for approval a properly prepared HACCP plan as specified under 12 VAC 5-421-3630 and the relevant provisions of this Chapter if:
 - 1. Submission of a HACCP plan is required according to law;
 - 2. A variance is required as specified under 12 VAC 5-421-860, 12 VAC 5-421-1300 B, or Subsections 12 VAC 5-421-440 B 2 b or 12 VAC 5-421-700 C 2; or
 - 3. The regulatory authority determines that a food preparation or processing method requires a variance based on a plan submittal specified under 12 VAC 5-421-3610, an inspectional finding, or a variance request.
- B. A permit applicant or permit holder shall have a properly prepared HACCP plan as specified under 12 VAC 5-421-870.

12 VAC 5-421-3630. Contents of a HACCP Plan.

8-201.14

For a food establishment that is required under 12 VAC 5-421-3620 to have a HACCP plan, the plan and specifications shall indicate:

- 1. A categorization of the types of potentially hazardous foods that are specified in the menu such as soups and sauces, salads, and bulk, solid foods such as meat roasts, or of other foods that are specified by the regulatory authority;
- 2. A flow diagram by specific food or category type identifying critical control points and providing information on the following:
 - a. Ingredients, materials, and equipment used in the preparation of that food, and
 - b. Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
- 3. Food employee and supervisory training plan that addresses the food safety issues of concern;
- 4. A statement of standard operating procedures for the plan under consideration including clearly identifying:
 - a. Each critical control point,
 - b. The critical limits for each critical control point,
 - c. The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge,
 - d. The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points,
 - e. Action to be taken by the person in charge if the critical limits for each critical control point are not met, and
 - f. Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed; and

5. Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.

12 VAC 5-421-3640. Confidentiality - Trade Secrets.

8-202.10

The regulatory authority shall treat as confidential in accordance with law, information that meets the criteria specified in law for a trade secret and is contained on inspection report forms and in the plans and specifications submitted as specified under 12 VAC 5-421-3610 and 12 VAC 5-421-3630.

12 VAC 5-421-3650. Preoperational Inspections.

8-203.10

The regulatory authority shall conduct one or more preoperational inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, has established standard operating procedures as specified under 12 VAC 5-421-3610 5 and is in compliance with law and this Chapter.

Part VIII

Compliance and Enforcement

Article 3

Permit to Operate

12 VAC 5-421-3660. Permits.

No person shall own, establish, conduct, maintain, manage, or operate any food establishment in this Commonwealth unless the food establishment is permitted as provided in this section. All permits shall be in the name of the owner or lessee. Permits shall not be issued to newly constructed or extensively remodeled food establishments until a certificate of occupancy has been issued by the Building Official. Only a person who complies with the requirements of this part shall be entitled to receive or retain such a permit.

- A. Nontransference of food establishment Permits. Permits issued shall not be transferable from one person to another or from one location to another. A new owner shall be required to make a written application for a permit. The application forms are obtainable at all local health departments.
- B. Expansion, Modification or Reclassification of a food establishment. Any person operating a food establishment with a valid permit who desires to expand or modify the establishment, shall notify the director in the jurisdiction where the food establishment is located, and the director shall determine

whether such expansion, modification, or reclassification is in compliance with the applicable sections of this part.

C. Requirements for Posting Permits. The permit shall be posted in every food establishment in a place where it is readily observable by the public transacting business with the establishment.

12 VAC 5-421-3670. Application Procedure, Submission 30 Calendar Days Before Proposed Opening. **8-302.11**

An applicant shall submit an application for a permit at least 30 calendar days before the date planned for opening a food establishment or the expiration date of the current permit for an existing facility.

12 VAC 5-421-3680. Form of Submission.

8-302.12

A person desiring to operate a food establishment shall submit to the regulatory authority a written application for a permit on a form provided by the regulatory authority.

8-302.13

To qualify for a permit, an applicant shall:

1. Be an owner of the food establishment or an officer of the legal ownership;

12 VAC 5-421-3690. Qualifications and Responsibilities of Applicants.

- 2. Comply with the requirements of this regulation; and
- 3. As specified under 12 VAC 5-421-3820, agree to allow access to the food establishment and to provide required information.

12 VAC 5-421-3700. Contents of the Application.

8-302.14

The application shall include:

- 1. The name, mailing address, telephone number, and signature of the person applying for the permit and the name, mailing address, and location of the food establishment;
- 2. Information specifying whether the food establishment is owned by an association, corporation, individual, partnership, or other legal entity;
- 3. A statement specifying whether the food establishment:

- a. Is mobile or stationary and temporary or permanent, and
- b. Is an operation that includes one or more of the following:
 - (1) Prepares, offers for sale, or serves potentially hazardous food:
 - (a) Only to order upon a consumer's request,
 - (b) In advance in quantities based on projected consumer demand and discards food that is not sold or served at an approved frequency, or
 - (c) Using time as the public health control as specified under 12 VAC 5-421-850,
 - (2) Prepares potentially hazardous food in advance using a food preparation method that involves two or more steps which may include combining potentially hazardous ingredients; cooking; cooling; reheating; hot or cold holding; freezing; or thawing,
 - (3) Prepares food as specified under Subsection 3 b 2 of this section for delivery to and consumption at a location off the premises of the food establishment where it is prepared,
 - (4) Prepares food as specified under Subsection 3 b 2 of this section for service to a highly susceptible population,
 - (5) Prepares only food that is not potentially hazardous, or
 - (6) Does not prepare, but offers for sale only prepackaged food that is not potentially hazardous;
- 4. The name, title, address, and telephone number of the person directly responsible for the food establishment;
- 5. The name, title, address, and telephone number of the person who functions as the immediate supervisor of the person specified under Subsection 4 of this section such as the zone, district, or regional supervisor;
- 6. The names, titles, and addresses of:
 - a. The persons comprising the legal ownership as specified under Subsection 2 of this section including the owners and officers, and

- b. The local resident agent if one is required based on the type of legal ownership;
- 7. A statement signed by the applicant that:
 - a. Attests to the accuracy of the information provided in the application, and
 - b. Affirms that the applicant will:
 - (1) Comply with this Chapter, and
 - (2) Allow the regulatory authority access to the establishment as specified under 12 VAC 5-421-3820 and to the records specified under 12 VAC 5-421-440 and 12 VAC 5-421-2330 and Subsection 12 VAC 5-421-3630 4 f; and
- 8. Other information required by the regulatory authority.

12 VAC 5-421-3710. New, Converted, or Remodeled Establishments. **8-303.10**

For food establishments that are required to submit plans as specified under 12 VAC 5-421-3600 the regulatory authority shall issue a permit to the applicant after:

- 1. A properly completed application is submitted;
- 2. Any required fee is submitted;
- 3. The required plans, specifications, and information are reviewed and approved; and
- 4. A preoperational inspection shows that the establishment is built or remodeled in accordance with the approved plans and specifications and that the establishment is in compliance with this Chapter.

12 VAC 5-421-3720. Existing Establishments, Permit Renewal, and Change of Ownership. **8-303.20**

The regulatory authority may renew a permit for an existing food establishment or may issue a permit to a new owner of an existing food establishment after a properly completed application is submitted, reviewed, and approved, any fees are paid, and an inspection shows that the establishment is in compliance with this Chapter.

12 VAC 5-421-3730. Denial of Application for Permit, Notice.

8-303.30

If an application for a permit to operate is denied, the regulatory authority shall provide the applicant with a notice that includes:

- 1. The specific reasons and chapter citations for the permit denial;
- 2. The actions, if any, that the applicant must take to qualify for a permit; and
- 3. Advisement of the applicant's right of appeal and the process and time frames for appeal that are provided in law.

12 VAC 5-421-3740. Responsibilities of the Regulatory Authority.

8-304.10

- A. At the time a permit is first issued, the regulatory authority shall provide to the permit holder a copy (or opportunity to obtain a copy) of this Chapter so that the permit holder is notified of the compliance requirements and the conditions of retention, as specified under 12 VAC 5-421-3750, that are applicable to the permit.
- B. Failure to provide the information specified in Subsection A of this section does not prevent the regulatory authority from taking authorized action or seeking remedies if the permit holder fails to comply with this Chapter or an order, warning, or directive of the regulatory authority.

12 VAC 5-421-3750. Responsibilities of the Permit Holder.

8-304.11

Upon acceptance of the permit issued by the regulatory authority, the permit holder in order to retain the permit shall:

- 1. Post the permit in a location in the food establishment that is conspicuous to consumers;
- 2. Comply with the provisions of this Chapter including the conditions of a granted variance as specified under 12 VAC 5-421-3590, and approved plans as specified under 12 VAC 5-421-3610;
- 3. If a food establishment is required under 12 VAC 5-421-3620 to operate under a HACCP plan, comply with the plan as specified under 12 VAC 5-421-3590;
- 4. Immediately contact the regulatory authority to report an illness of an applicant or employee as specified under 12 VAC 5-421-120;

- 5. Immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist as specified under 12 VAC 5-421-3910;
- 6. Allow representatives of the regulatory authority access to the food establishment as specified under 12 VAC 5-421-3820;
- 7. Except as specified under Subsection 8 of this section, replace existing facilities and equipment specified in 12 VAC 5-421-3510 with facilities and equipment that comply with this Chapter if:
 - a. The regulatory authority directs the replacement because the facilities and equipment constitute a public health hazard or nuisance or no longer comply with the criteria upon which the facilities and equipment were accepted,
 - b. The regulatory authority directs the replacement of the facilities and equipment because of a change of ownership, or
 - c. The facilities and equipment are replaced in the normal course of operation;
- 8. Upgrade or replace refrigeration equipment as specified under 12 VAC 5-421-820 3, if the circumstances specified under Subsections 7 a through c of this section do not occur first, and 5 years pass after the regulatory authority adopts this Chapter;
- 9. Comply with directives of the regulatory authority including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives issued by the regulatory authority in regard to the permit holder's food establishment or in response to community emergencies;
- 10. Accept notices issued and served by the regulatory authority according to law; and
- 11. Be subject to the administrative, civil, injunctive, and criminal remedies authorized in law for failure to comply with this Chapter or a directive of the regulatory authority, including time frames for corrective actions specified in inspection reports, notices, orders, warnings, and other directives.

12 VAC 5-421-3760. Permits Not Transferable.

8-304.20

A permit may not be transferred from one person to another person, from one food establishment to another, or from one type of operation to another if the food operation changes from the type of operation specified in the application as specified under 12 VAC 5-421-3700 and the change in operation is not approved.

12 VAC 5-421-3770. Suspension of a permit.

The director may suspend without a hearing a permit to operate a restaurant if the director finds the continued operation constitutes a substantial and imminent threat to the public health, except the director may suspend the permit of a temporary restaurant as addressed under 12 VAC 5-421-3870. Upon receipt of such notice that a permit is suspended, the permit holder shall cease food operations immediately and begin corrective action.

Whenever a permit is suspended, the holder of the permit or the person in charge shall be notified in writing by certified mail or by hand delivery. Upon service of notice that the permit is immediately suspended, the former permit holder shall be given an opportunity for a hearing. The request for a hearing shall be in writing. The written request shall be filed with the local department by the former holder of the permit. If written request for a hearing is not filed within ten working days, the suspension is sustained. Each holder of a suspended permit shall be afforded an opportunity for an informal hearing, within three working days of receipt of a request for the hearing. The director may end the suspension at any time if the reasons for the suspension no longer exist.

12 VAC 5-421-3780. Revocation of a permit.

The director may, after providing an opportunity for a hearing, revoke a permit for flagrant or continuing violation of any of the requirements of this part.

Prior to revocation, the director shall notify in writing the holder of the permit, or the person in charge, of the specific reason for which the permit is to be revoked. The permit shall be revoked at the end of the fifteen days following service of such notice unless a written request for a hearing is filed before then with the director from which the permit was obtained. If no request for a hearing is filed within the fifteen day period, the revocation of the permit shall be final.

12 VAC 5-421-3790. Application after revocation.

Any person whose permit has been revoked, may apply for a new permit by following the procedures of this part outlined in 12 VAC 5-421-3670 through 3700.

Part VIII

Compliance and Enforcement

Article 4

Inspection and Correction of Violations

12 VAC 5-421-3800. Periodic inspection.

8-401.10

Food establishments shall be inspected by the designee of the director. Inspections of the food establishments shall be performed as often as necessary for the enforcement of this part in accordance with the following:

- 1. Except as specified in Subsection 2 and 3 of this section, the regulatory authority shall inspect a food establishment at least once every 6 months.
- 2. The regulatory authority may increase the interval between inspections beyond 6 months if:
 - a. The food establishment is fully operating under an approved and validated HACCP plan as specified under 12 VAC 5-421-3630 and 12 VAC 5-421-3570 A and B;
 - b. The food establishment is assigned a less frequent inspection frequency based on a written risk-based inspection schedule that is being uniformly applied throughout the jurisdiction and at least once every 6 months the establishment is contacted by telephone or other means by the regulatory authority to ensure that the establishment manager and the nature of the food operation are not changed; or,
 - c. The establishment's operation involves only coffee service and other unpackaged or prepackaged food that is not potentially hazardous such as carbonated beverages and snack food such as chips, nuts, popcorn, and pretzels.
- 3. The regulatory authority shall periodically inspect throughout its permit period a temporary food establishment that prepares, sells, or serves unpackaged potentially hazardous food and that:
 - a. Has improvised rather than permanent facilities or equipment for accomplishing functions such as handwashing, food preparation and protection, food temperature control, warewashing, providing drinking water, waste retention and disposal, and insect and rodent control; or

b. Has inexperienced food employees.

12 VAC 5-421-3810. Performance- and Priority-Based Inspections.

8-401.20

Within the parameters specified in 12 VAC 5-421-3800, the regulatory authority shall prioritize, and conduct more frequent inspections based upon its assessment of a food establishment's history of compliance with this Chapter and the establishment's potential as a vector of foodborne illness by evaluating:

- 1. Past performance, for nonconformance with this chapter or HACCP plan requirements that are critical;
- 2. Past performance, for numerous or repeat violations of this chapter or HACCP plan requirements that are noncritical;
- 3. Past performance, for complaints investigated and found to be valid;
- 4. The hazards associated with the particular foods that are prepared, stored, or served;
- 5. The type of operation including the methods and extent of food storage, preparation, and service;
- 6. The number of people served; and
- 7. Whether the population served is a highly susceptible population.

12 VAC 5-421-3820. Access Allowed at Reasonable Times after Due Notice. **8-402.11**

After the regulatory authority presents official credentials and provides notice of the purpose of, and an intent to conduct, an inspection, the person in charge shall allow the regulatory authority to determine if the food establishment is in compliance with this Chapter by allowing access to the establishment, allowing inspection, and providing information and records specified in this Chapter and to which the regulatory authority is entitled according to law, during the food establishment's hours of operation and other reasonable times.

12 VAC 5-421-3830. Refusal, Notification of Right to Access, and Final Request for Access. **8-402.20**

If a person denies access to the regulatory authority, the regulatory authority shall:

1. Inform the person that:

- a. The permit holder is required to allow access to the regulatory authority as specified under 12 VAC 5-421-3820 of this Chapter,
- b. Access is a condition of the acceptance and retention of a food establishment permit to operate as specified under 12 VAC 5-421-3750 6, and
- c. If access is denied, the commissioner or his designee may apply to an appropriate circuit court for an inspection warrant authorizing such inspection, testing, or taking samples for testing as provided chapter 24 (19.2-393 et seq) of Title 19.2 of the Code of Virginia; and
- 2. Make a final request for access.

12 VAC 5-421-3840. Refusal, Reporting.

8-402.30

If after the regulatory authority presents credentials and provides notice as specified under 12 VAC 5-421-3820, explains the authority upon which access is requested, and makes a final request for access as specified in 12 VAC 5-421-3830, the person in charge continues to refuse access, the regulatory authority shall provide details of the denial of access on an inspection report form.

12 VAC 5-421-3850. Inspection Warrants.

If denied access to a food establishment for an authorized purpose and after complying with 12 VAC 5-421-3830, the commissioner or his designee may apply to an appropriate circuit court for an inspection warrant authorizing such inspection, testing, or taking samples for testing as provided chapter 24 (19.2-393 et seq) of Title 19.2 of the Code of Virginia.

12 VAC 5-421-3860. Documenting Information and Observations.

8-403.10

The regulatory authority shall document on an inspection report form:

- 1. Administrative information about the food establishment's legal identity, street and mailing addresses, type of establishment and operation as specified under 12 VAC 5-421-3700 3, inspection date, and other information such as type of water supply and sewage disposal, status of the permit, and personnel certificates that may be required; and
- 2. Specific factual observations of violative conditions or other deviations from this Chapter that require correction by the permit holder including:

- a. Failure of the person in charge to demonstrate the knowledge of foodborne illness prevention, application of HACCP principles, and the requirements of this Chapter specified under 12 VAC 5-421-60,
- b. Failure of food employees and the person in charge to demonstrate their knowledge of their responsibility to report a disease or medical condition as specified under 12 VAC 5-421-110 and 12 VAC 5-421-120,
- c. Nonconformance with critical items of this Chapter,
- d. Failure of the appropriate food employees to demonstrate their knowledge of, and ability to perform in accordance with, the procedural, monitoring, verification, and corrective action practices required by the regulatory authority as specified under 12 VAC 5-421-60,
- e. Failure of the person in charge to provide records required by the regulatory authority for determining conformance with a HACCP plan as specified under Subsection 12 VAC 5-421-3630 4 f, and
- f. Nonconformance with critical limits of a HACCP plan.

12 VAC 5-421-3870. Specifying Time Frame for Corrections.

8-403.20

The regulatory authority shall specify on the inspection report form the time frame for correction of the violations as specified under 12 VAC 5-421-3910, 12 VAC 5-421-3930, and 12 VAC 5-421-3950. In the case of temporary food establishments, all violations shall be corrected within a maximum of 24 hours or the permit shall be suspended. The establishment shall immediately cease food service operations until authorized to resume by the director.

12 VAC 5-421-3880. Issuing Report and Obtaining Acknowledgment of Receipt. **8-403.30**

At the conclusion of the inspection and according to law, the regulatory authority shall provide a copy of the completed inspection report and the notice to correct violations to the permit holder or to the person in charge, and request a signed acknowledgment of receipt.

12 VAC 5-421-3890 Refusal to Sign Acknowledgment.

8-403.40

The regulatory authority shall:

1. Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in 12 VAC 5-421-3880 that:

- a. An acknowledgment of receipt is not an agreement with findings,
- b. Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified, and
- c. A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the regulatory authority's historical record for the food establishment; and
- 2. Make a final request that the person in charge sign an acknowledgment receipt of inspectional findings.

12 VAC 5-421-3900. Public Information.

8-403.50

Except as specified in 12 VAC 5-421-3640, the regulatory authority shall treat the inspection report as a public document and shall make it available for disclosure to a person who requests it as provided in law.

12 VAC 5-421-3910. Imminent Health Hazard, Ceasing Operations and Reporting. **8-404.11**

A. Except as specified in Subsection B of this section, a permit holder shall immediately discontinue operations and notify the regulatory authority if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross insanitary occurrence or condition, or other circumstance that may endanger public health.

B. A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

12 VAC 5-421-3920. Resumption of Operations.

8-404.12

If operations are discontinued as specified under 12 VAC 5-421-3910 or otherwise according to law, the permit holder shall obtain approval from the regulatory authority before resuming operations.

12 VAC 5-421-3930. Critical Violation, Timely Correction.

8-405.11

A. Except as specified in Subsection B of this section, a permit holder shall at the time of inspection correct a critical violation of this Chapter and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.

B. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the regulatory authority may agree to or specify a longer time frame, not to exceed 10 calendar days after the inspection, for the permit holder to correct critical violations or HACCP plan deviations.

12 VAC 5-421-3940. Verification and Documentation of Correction.

8-405.20

- A. After observing at the time of inspection a correction of a critical violation or deviation, the regulatory authority shall enter the violation and information about the corrective action on the inspection report.
- B. As specified under 12 VAC 5-421-3930 B, after receiving notification that the permit holder has corrected a critical violation or HACCP plan deviation, or at the end of the specified period of time, the regulatory authority shall verify correction of the violation, document the information on an inspection report, and enter the report in the regulatory authority's records.

12 VAC 5-421-3950. Noncritical Violation, Time Frame for Correction.

8-406.11

- A. Except as specified in Subsection B of this section, the permit holder shall correct noncritical violations by a date and time agreed to or specified by the regulatory authority but no later than 90 calendar days after the inspection.
- B. The regulatory authority may approve a compliance schedule that extends beyond the time limits specified under Subsection A of this section if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

12 VAC 5-421-3960. Examination for condemnation of food.

Food may be examined or sampled by the department as often as necessary for enforcement of this part. Also, the department may, upon written notice to the owner or permit holder or person in charge impound any food which it believes is in violation of Part III or any other section of this part. The department shall tag, label, or otherwise identify any food subject to impoundment. No food under conditions specified in the impoundment shall be used, served or moved from the establishment. The department shall permit storage of the food under conditions specified in the impoundment unless storage is not possible without risk to the public health in which case immediate destruction shall be ordered and accomplished. The impoundment shall state that a request for a hearing may be filed within ten days and that if no hearing is requested, the food shall be destroyed. A hearing shall be held if so requested, and on the basis of evidence produced at the hearing, the impoundment may be vacated, or

the owner or permit holder or person in charge of the food may be directed by written order to denature or destroy such food or to bring it into compliance with the provisions of this part.

12 VAC 5-421-3970. Enforcement of regulation.

This part shall be enforced by the State Board of Health and the State Health Commissioner, as executive officer of the board.

The directors are appointed by the board and commissioner as duly designated officers and are responsible for the implementation and enforcement of this part.

- A. General. All restaurants shall operate in compliance with the requirements set forth in this part and shall not operate without a valid permit.
- B. Commissioner Vested with Board's Authority. The commissioner shall be vested with all the authority of the board when it is not in session, subject to such rules and regulations as may be prescribed by the board.
- C. Orders. Pursuant to the authority granted in §§ 32.1-26 and 35.1-6 of the Code of Virginia, the commissioner may issue orders to require any owner or permit holder, or other person, to comply with the provisions of these regulations. The order may require the following:
 - 1. The immediate cessation and correction of the violation;
 - 2. Appropriate remedial action to ensure that the violation does not continue or recur;
 - 3. The submission of a plan to prevent future violations;
 - 4. The submission of an application for a variance; and
 - 5. Any other corrective action deemed necessary for proper compliance with the regulations.
- D. Hearing before the issuance of an order. Before the issuance of an order, the commissioner must comply with the requirements of § 32.1-6 of the Code of Virginia.
- E. Order when effective. All orders issued pursuant to 12 VAC 5-421-3970 C shall become effective not less than 15 days after mailing a copy thereof by certified mail to the last known address of the owner or permit holder or person violating these regulations. Violation of an order is a class 3 misdemeanor. See § 32.1-7 of the Code of Virginia.

- F. Compliance. The commissioner may act as the agent of the board to enforce all effective orders and these regulations. Should any owner or permit holder fail to comply with any effective order or these regulations, the commissioner may:
 - 1. Institute a proceeding to revoke the owner or permit holder's permit in accordance with 12 VAC 5-421-3780; or
 - 2. Request the attorney for the Commonwealth to bring a criminal action; or
 - 3. Request the Attorney General to bring an action for civil penalty, injunction, or other appropriate remedy; or
 - 4. Do any combination of the above.
- G. Not exclusive means of enforcement. Nothing contained in 12 VAC 5-421-3970 shall be interpreted to require the commissioner to issue an order prior to seeking enforcement of any regulations or statute through an injunction, mandamus or criminal prosecution.
- H. Hearings before the commissioner or his designee shall include any of the following forms depending on the nature of the controversy and the interests of the parties involved.
 - 1. Informal hearings. An informal hearing is a meeting with a district or local health department with the district or local health director presiding and held in conformance with § 9-6.14:11 of the Code of Virginia.
 - 2. Adjudicatory hearing. The adjudicatory hearing is a formal, public adjudicatory proceeding before the commissioner, or his designated hearing officer, and held in conformance with § 9-6.14:12 of the Code of Virginia.

12 VAC 5-421-3980. Request for Hearing.

A request for an informal hearing shall be made by sending the request in writing to the district or local health department in the locality where the food establishment is located. Requests for hearings shall cite the reason(s) for the hearing request and shall cite the section(s) of these regulations involved and must be received within 30 days of the decision by the department that lead to the hearing request.

12 VAC 5-421-3990. Hearing as a Matter of Right.

Any owner or permit holder or named party whose rights, duties, or privileges have been, or may be affected by any case decision of the board or its subordinates in the administration of these

regulations shall have a right to both informal and adjudicatory hearings. The commissioner may require participation in an informal hearing before granting the request for a full adjudicatory hearing. Exception: No person other than an owner shall have the right to an adjudicatory hearing to challenge the issuance of a permit to operate unless the person can demonstrate at an informal hearing that the minimum standards contained in these regulations have not been applied and that he will be injured in some manner by the issuance of the permit.

12 VAC 5-421-4000. Appeals.

Any appeal from a denial of a permit to operate a food establishment must be made in writing and received by the department within 30 days of the date the denial letter was received.

- 1. Any request for hearing on the denial of an application for a variance pursuant to 12 VAC 5-421-3590 A must be made in writing and received within sixty days of receipt of the denial notice.
- 2. Any request for a variance must be made in writing and received by the department prior to the denial of the food establishment permit, or within 60 days after such denial.
- 3. In the event a person applies for a variance within the 60 day period provided by paragraph 2 above, the date for appealing the denial of the permit, pursuant to paragraph A above, shall commence from the date on which the department acts on the request for a variance.
- 4. Pursuant to the Administrative Process Act (§ 9-6.14:1 et. seq.. of the Code of Virginia) an aggrieved owner or permit holder may appeal a final case decision of the commissioner to an appropriate circuit court.

12 VAC 5-421-4010. Penalties, Injunctions, Civil Penalties and Charges for Violations.

- A. Any person willfully violating, or refusing, failing, or neglecting to comply with any regulations or order of the board or commissioner, or any provision of this title, shall be guilty of a Class 3 misdemeanor unless a different penalty is specified. Each day of violation shall constitute a separate offense.
- B. Any person violating, or failing, neglecting, or refusing to obey any order of the board or commissioner, or any provision of this part may be compelled, in a proceeding instituted in an appropriate court by the board or commissioner, to obey and comply with such regulations, order, or any applicable provision of Title 35.1 of the Code of Virginia. The proceeding may be by injunction, mandamus, or other appropriate remedy.

- C. Without limiting the remedies which may be obtained pursuant to the above subsection, any person violating or failing, neglecting, or refusing to obey any injunction, mandamus, or other remedy obtained pursuant to the above subsection shall be subject, in the discretion of the court, to a civil penalty not to exceed ten thousand dollars for each violation. Each day of violation shall constitute a separate offense.
- D. With the consent of any person who has violated or failed, neglected or refused to obey any regulation or order of the board or commissioner or any applicable provision of Title 35.1, the board may provide, in an order issued by the board against such person, for the payment of civil charges for past violations in specific sums not to exceed the limit set forth in the above subsection. Such civil charges shall be in place of any appropriate civil penalty which could be imposed under the above subsection.

12 VAC 5-421-4020. Compliance with the Uniform Statewide Building Code.

All buildings or structures utilized as restaurants constructed prior to the effective date of the Virginia Uniform Statewide Building Code shall be maintained in conformance with the Virginia Fire Safety Law or other code in effect at the time of construction.

12 VAC 5-421-4030. Local ordinance superseded-exception.

The regulations of the board shall supersede all local ordinances regulating restaurants other than those adopted pursuant to the provisions of § 35.1-26, Code of Virginia, except that any locality may adopt ordinances regarding (i) the sale, preparation, and handling of food provided such ordinances are equivalent to, or more stringent in regard to public health, than the applicable provisions of Title 35.1, and the regulations of the board. Where local ordinances prevail, local permits may be issued as required by the local ordinances. However, this does not preclude the requirement to issue a department permit before providing food services for the public.

12 VAC 5-421-4040 Investigation and Control, Obtaining Information: Personal History of Illness, Medical Examination, and Specimen Analysis.

8-501.10

The regulatory authority shall act when it has reasonable cause to believe that a food employee has possibly transmitted disease; may be infected with a disease in a communicable form that is transmissible through food; may be a carrier of infectious agents that cause a disease that is transmissible through food; or is affected with a boil, an infected wound, or acute respiratory infection, by:

1. Securing a confidential medical history of the employee suspected of transmitting disease or making other investigations as deemed appropriate; and

2. Requiring appropriate medical examinations, including collection of specimens for laboratory analysis, of a suspected employee and other employees.

12 VAC 5-421-4050. Restriction or Exclusion of Food Employee, or Summary Suspension of Permit.

Based on the findings of an investigation related to a food employee who is suspected of being infected or diseased, the regulatory authority may issue an order to the suspected food employee or permit holder instituting one or more of the following control measures:

- 1. Restricting the food employee's services to specific areas and tasks in a food establishment that present no risk of transmitting the disease;
- 2. Excluding the food employee from a food establishment; or
- 3. Closing the food establishment by summarily suspending a permit to operate in accordance with law.

12 VAC 5-421-4060 Restriction or Exclusion Order: Warning or Hearing Not Required, Information Required in Order. **8-501.30**

Based on the findings of the investigation as specified in 12 VAC 5-421-4040 and to control disease transmission, the regulatory authority may issue an order of restriction or exclusion to a suspected food employee or the permit holder without prior warning, notice of a hearing, or a hearing if the order:

- 1. States the reasons for the restriction or exclusion that is ordered;
- 2. States the evidence that the food employee or permit holder shall provide in order to demonstrate that the reasons for the restriction or exclusion are eliminated;
- 3. States that the suspected food employee or the permit holder may request an appeal hearing by submitting a timely request as provided in law; and
- 4. Provides the name and address of the regulatory authority representative to whom a request for an appeal hearing may be made.

12 VAC 5-421-4070. Release of Food Employee from Restriction or Exclusion. **8-501.40**

The regulatory authority shall release a food employee from restriction or exclusion according to law and the following conditions:

- 1. A food employee who was infected with Salmonella typhi if the food employee's stools are negative for S. typhi based on testing of at least 3 consecutive stool specimen cultures that are taken:
 - a. Not earlier than 1 month after onset,
 - b. At least 48 hours after discontinuance of antibiotics, and
 - c. At least 24 hours apart; and
- 2. If one of the cultures taken as specified in Subsection 1 of this section is positive, repeat cultures are taken at intervals of 1 month until at least 3 consecutive negative stool specimen cultures are obtained.
- 3. A food employee who was infected with Shigella spp. or Escherichia coli O157:H7 if the food employee's stools are negative for Shigella spp. or E. coli O157:H7 based on testing of 2 consecutive stool specimen cultures that are taken:
 - a. Not earlier than 48 hours after discontinuance of antibiotics; and
 - b. At least 24 hours apart.
- 4. A food employee who was infected with hepatitis A virus if:
 - a. Symptoms cease; or
 - b. At least 2 blood tests show falling liver enzymes.